THE PREVALENCE OF LONG-TERM OTITIS MEDIA RELATED HEARING LOSS IN CHILDREN AND ITS IMPACT ON DEVELOPMENTAL OUTCOMES

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June 2021

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2021

Thesis summary

Otitis media (OM) is a common cause of temporary hearing loss (HL) in childhood. However, for some children it may result in long-term HL lasting more than 3 months. Epidemiological studies of HL in childhood generally focus on permanent hearing impairment and not that due to OM. Therefore, the prevalence of long-term OM related HL is unknown as well as the potential impact that it may have on children's development.

This research aims to 1) systematically review existing literature on the impact of long-term OM related HL on cognition and academic ability; 2) determine the prevalence of long-term OM related HL in the Avon Longitudinal Study of Parents and Children (ALSPAC) and 3) study the impact on cognitive, educational and mental health outcomes.

The systematic review revealed weak evidence of long-term OM related HL having a negative impact on IQ and academic ability. In the ALSPAC study the prevalence of long-term OM related HL was 2.69% over the ages 7-15 years. This group had poorer IQ scores at age 15 than children without HL (verbal IQ: -4.72; performance IQ: -1.48). No associations were found with academic achievement at 15-16 years or anxiety and depression at 10 and 15 years.

These findings indicate that the prevalence of long-term OM related HL is approximately 20 times higher than permanent HL in childhood. Furthermore, this HL has been shown to negatively impact cognition. Additional research is required to investigate the impact of this HL further and to determine how children can be better supported by clinical and educational services. A qualitative study design for future work using ethnographic and grounded theory methods to address this is presented.

Key words: otitis media with effusion, childhood hearing loss, prospective cohort study, cognition, psychosocial

ACKNOWLEDGEMENTS

In the name of The Most Gracious, The Most Beneficent.

First and foremost, I would like to thank the Almighty Lord for allowing me to embark on this journey and produce this work. My faith has been pivotal on this journey and I am grateful for the growth that has occurred, both professionally and personally.

I would like to express my sincere gratitude and hearty thanks to my wonderful supervisor, Dr Amanda Hall for her guidance, support, patience and mentorship. For providing me with this opportunity and inspiring me with her passion and work ethic. It has been a great pleasure to have her as a supervisor and friend over the last few years.

I would also like to thank my two associate supervisors, Dr Helen Pryce-Cazalet and Dr Rachel Shaw for their valued involvement, time and feedback, even during the most difficult times. I am grateful to have had such a great supervisory team.

A special thanks to my parents and three sisters who first encouraged me to begin this research programme and who continued to provide this encouragement over the past three years. They have been my support system and motivation. Thank you for believing in me and always pushing me to reach my potential. Also, a warm thanks to my friends who have stayed on this journey with me, providing words of encouragement, moral support and much needed laughter along the way.

Finally, I wish to thank all of the families who took part in ALSPAC and all of the members of the ALSPAC team involved in study set-up, recruitment and data collection, as well as those involved in making the data available to me and dealing with enquiries.

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Chapter 1. Introduction

In this thesis, I present research which investigates the prevalence of long-term otitis media (OM) related hearing loss (HL) in children and adolescents aged between 7 and 15 years and the impact that this HL has on their development. OM is a condition affecting the middle ear that commonly occurs during childhood (Kubba et al., 2000; Bluestone, 2003). Although in most cases it is temporary in nature, in some cases the condition persists (NICE, 2016; Bluestone, 2003). Symptoms of OM may include HL, which resolves upon resolution of OM (O'Connor et al., 2016; Bluestone, 2003). However, in cases where OM persists, HL may be present over the long-term.

The work presented in this thesis aims firstly, to determine the prevalence of this long-term OM related HL by analysing data from a large longitudinal birth cohort study, in order to provide epidemiological information on this form of HL. The second aim of this research is to explore the impact of this HL in the context of psychosocial and cognitive development and educational outcomes. This is approached through conducting a systematic review on the current literature, followed by secondary data analysis using data from the longitudinal birth cohort study. By utilising longitudinal data, the aim is to examine the prevalence and impact at multiple time points, taking a life course approach as it is unclear whether this 'childhood' condition has any long-term effects.

1.1. Structure of the thesis

This thesis comprises a further two introductory chapters. Chapter 2 entails an overview of the literature surrounding OM related HL in terms of epidemiology and potential impact on child development, identifying gaps in current knowledge. Chapter 3 proposes the relevant research questions and aims and covers the research plan and approach to answer the proposed questions.

Chapter 4 presents the systematic review of the current literature, focusing on the impact of long-term OM related HL on cognitive and academic outcomes. Chapters 5, 6 and 7 focus on the analysis of data from the longitudinal birth cohort study, with Chapter 5 providing the initial introduction to this study and describing the hearing data available. The descriptive analysis of the data to estimate the prevalence of long-term OM related HL is presented in Chapter 6. Chapter 7 includes further analysis of the data to investigate associations between long-term OM related HL and cognitive, educational and mental health outcomes.

Before moving onto the discussion of this work, this thesis includes a chapter on supplementary research that can be carried out to explore the impact of long-term OM related HL further and to more specifically focus on the information and support needs of children (and their families) who present with long-term OM related HL. This work outlined in Chapter 8, moves away from the quantitative approach taken by the work presented in this thesis and is designed to utilise qualitative methods to provide a deeper understanding of how the condition may impact children, and their required support needs.

Finally, in Chapter 9 discussion of key findings and their implications are presented. The strengths and limitations of this work are also outlined along with final suggestions for future work, followed by conclusion of this thesis.

References and appendices can be found at the end of this thesis.

Chapter 2. Thesis background

2.1 Introduction

This chapter introduces the purpose of this research, discussing the gaps in knowledge and the rationale for studying the prevalence of long-term otitis media (OM) related hearing loss (HL) and its impact. Knowledge of OM and HL in childhood is reviewed as well as the potential impact of the HL on psychosocial functioning and cognition.

2.2 Childhood hearing loss & otitis media

This section introduces the types of childhood HL, then gives the background for studying long-term OM related HL by introducing OM and childhood HL.

Hearing levels are measured in decibels (dB) and severity of HL is categorised according to whether the HL is mild, moderate, severe or profound. Normal hearing ranges from <0 to 20 dB HL (decibel hearing level). A mild HL constitutes hearing levels between 21 to 40 dB HL, moderate 41 to 70 dB HL, severe 71 to 95 dB HL and profound >95 dB HL (BSA, 2018). The severity of the effect of HL increases with severity of HL as shown in Table 2.1 (WHO, 2016).

Table 2.1 Degrees of hearing loss and their impact (BSA, 2018) (WHO, 2016)

Degree of hearing loss	**Hearing level (dB)**	**Characteristics of hearing loss**
Mild	21 to 40	Difficulty with hearing soft speech sounds, speech from a distance or speech in the presence of background noise.
Moderate	41 to 70	Difficulty with hearing regular speech at close distances
Severe	71 to 95	Most conversational speech is not heard, and individual may have difficulty in hearing loud speech or loud environmental sounds.
Profound	>95	Cannot hear loud speech and environmental sounds. Loud sounds may be perceived through vibrations.

Hearing loss can be split into three types: conductive, sensorineural or mixed (Dimitrov and Gossman, 2021). A conductive HL refers to a hearing impairment that has occurred due to there being a problem with the transmission of sound within the external or middle ear. Sensorineural HL results from a disruption to sound transmission through the auditory pathway from the inner ear (cochlea) to the brainstem. A mixed HL refers to HL with both conductive and sensorineural elements. While most conductive hearing losses can be reversed, sensorineural HL is permanent (Dimitrov and Gossman, 2021).

2.2.1 Permanent hearing loss

Permanent HL in childhood can have implications for a child's speech and language development, cognitive functions, educational performance and attainment, social functioning and mental health (Yoshinaga-Itano et al., 1998; Stadio et al., 2020; Ching et al., 2019; LeClair and Saunders, 2019; Taylor and Sternberg, 1989; Theunissen et al., 2014; Hancock et al., 2017; Lieu et al., 2020). With a

wide range of potential impact on development, early identification and intervention is key in ensuring that children overcome these implications (Downs and Yoshinaga-Itano, 1999; Yoshinaga-Itano et al., 2020; Yoshinaga-Itano, 1999; Moeller, 2000; Yoshinaga-Itano, 2003; WHO, 2016).

The introduction of universal new-born hearing screening has enabled identification of permanent HL at birth and thus has enabled early intervention. Through new-born hearing screening 1.1 per 1000 new-borns are identified as having permanent HL >26dB HL (Butcher et al., 2019). Prevalence of childhood HL has been found to rise with age. Estimates of permanent childhood hearing impairment range from 1.33/1000 live births in children aged 5 years and older to 1.65/1000 births in children aged 9 years and older (Fortnum et al.; Fortnum et al., 2001).

More commonly than permanent HL, children can also have temporary HL typically due to OM. Around 45,000 - 50,000 children in the UK alone have some form and degree of HL (National Deaf Children's Society, 2019; Brown, 2020). Due to the temporary nature of the HL, children with HL associated with OM are not as widely included in research on childhood HL as children with permanent HL are.

2.2.2 Otitis media

A major cause of acquired mild to moderate HL in childhood is OM. OM refers to an inflammation of the middle ear, and is generally used as an umbrella term to refer to the various types and stages of OM. The term otitis media does not give any reference to the aetiology or pathogenesis of the middle ear inflammation which differs with the type of OM acquired. Two common distinct forms of OM are acute otitis media (AOM) and otitis media with effusion (OME) (Bluestone, 2003). The focus of this thesis is on OME.

2.2.2.1 Otitis media with effusion

OME, also known as 'glue ear', refers to a fairly asymptomatic effusion in the middle ear (Bluestone, 2003). It is a non-infective condition as opposed to AOM, where the middle ear fluid is infectious. Generally, this effusion present in OME does not result in any major symptoms, however, symptoms that may be present include a feeling of fullness in the ear, mild discomfort and mild HL (O'Connor et al., 2016). HL associated with OM is characteristically as a result of OME. OME is very commonly acquired by children and is the most common cause of HL in childhood in developed countries (Kubba et al., 2000). However, it is typically a temporary condition that should spontaneously resolve within 3 months (NICE, 2016). It is when OME results in a prolonged hearing impairment that it becomes more of a concern.

2.2.3 Epidemiology of otitis media

Most epidemiological studies on OM do not distinguish between the different types of OM so reported prevalence and incidence rates of OM include cases of AOM and OME. Some studies also include chronic suppurative OM (CSOM) which is characterised by a perforated tympanic membrane (eardrum) and discharging ear and may result as a complication of AOM or OME (Bluestone, 2003). Prevalence rates of OME have been reported as being as high as 20% at 2 years (Zielhuis et al., 1990). By the age of 5 years, up to 80% of children will have had an episode of OME (Williamson, 2007). The prevalence of OME generally declines with age. In a longitudinal study of OME in children up to the age of 5 years, prevalence of OME at 8 months was between 16.4 - 36.6% whereas at age 5 it had reduced and ranged between 3.1 - 16% (Midgley et al., 2000).

By 7 years, the prevalence of OME has been reported to fall between 3-8% (Simpson et al., 2007). A large Danish birth cohort study involving 95,095 full term pregnancies, reported a cumulative incidence for OM of 60.6% by 7 years. Four or more episodes of OM were reported by 0.3%, 13.6% and 23.9% of children at 6 months, 18 months, and 7 years, respectively (Todberg et al., 2014). Nevertheless, although this is the largest epidemiological cohort study on OM in the world providing longitudinal epidemiological data, data on OM in this study was obtained through parental report and not objectively assessed. The findings indicate a small percentage of children experiencing recurrent OM between the ages of 6 months and 7 years, but do not report on HL. As the findings from these studies indicate, OM is a lot more common in early childhood and thus is generally not studied past the age of 7 years.

2.3 Long-term OM related hearing loss

OME typically spontaneously resolves within 4 to 6 weeks, thus children who present with OME are initially placed under a 3-month period of watchful waiting (NICE, 2016). If OME and HL persists beyond this 3-month period, treatment is considered. Treatment involves either a surgical route or non-surgical route e.g. hearing aids or surgical insertion of grommets after which HL may or may not persist and require further intervention (NICE, 2016). This section now focuses on long-term OM related HL, highlighting the importance of studying the condition.

Although in some cases, OM can result in sensorineural hearing loss (SNHL) or mixed hearing loss, most HL associated with OM is a result of impairment of the functioning of the middle ear, therefore is commonly conductive (Bluestone, 2003; Williamson, 2007). With OME, as the level of fluid build-up is not consistent, hearing levels may fluctuate and hence may differ between ears, resulting in asymmetric HL (Kubba et al., 2000; Whitton and Polley, 2011). The HL may be of either a mild or

moderate degree, not exceeding 60dB (Bluestone, 2003). The average HL associated with OME is 27dB (Fria et al., 1985). This HL is temporary as once the middle ear effusion resolves, hearing thresholds usually return to normal levels (Bluestone, 2003). Negative pressure in the middle ear, which can be present when the effusion clears, can also cause conductive hearing loss (CHL) (Finkelstein et al., 1992). HL may become permanent however, as a result of chronic inflammation and infection, and further complications of OM or OM treatment such as chronic perforation of the eardrum, eardrum scarring or tympanosclerosis, cholesteatoma and mastoiditis (Bluestone, 2003; Williamson, 2007).

While more than 50% of OME cases resolve within 3 months, it is estimated that it recurs in 30-40% of children over several years with only 33% of cases resolving within 2 years (Rosenfeld and Kay, 2003). OME which lasts longer than 3 months with HL has been referred to as chronic OME (Walker et al., 2017). However, it is not typically thought of as a chronic or long-term condition due to the emphasis on OME being a common temporary condition that occurs in childhood. For example, on the NHS website, glue ear is reported as being a potential cause of *temporary* HL stating that glue ear usually resolves within 3 months (NHS, 2020). Furthermore, it is advised to see a specialist if issues with hearing are noticed or if there are noticeable effects on a child's learning and development (NHS, 2020). HL and its implications may not be noticeable in the first instance due to the mild and fluctuating nature of the HL. Thus, intervention and support for the child may be delayed.

At present, if children still present in clinics with OME and the associated HL after the observation period, they remain under clinical care and may receive treatment. As there is no cure, treatment may continually be provided to manage the condition. However, multiple lots of treatment comes with its risk of complications in itself. These include perforation of the eardrum from grommet insertion and infection which may ultimately affect other parts of the ear/temporal bone; consequently adding to the effects of OME and HL (Djordjevic et al., 2015; Maw and Bawden, 1994;

Schilder, 1999; Paparella et al., 2002; O'Connor et al., 2009). Furthermore, contemporary hearing aids do not result in resolution of OME and have the risk of resulting in further infections (Samra, 2018; Chasin, 2002; Dawe et al., 2019). In cases where long-term OME leads to permanent HL due to permanent damage to the middle ear, bone conduction hearing aids may be the best option (Samra, 2018; Chasin, 2002; Dawe et al., 2019).

Keeping this in mind, a long-term or chronic health condition is defined as one which requires clinical follow-up for >12 months in 50% or more of cases and which may affect many aspects of children's

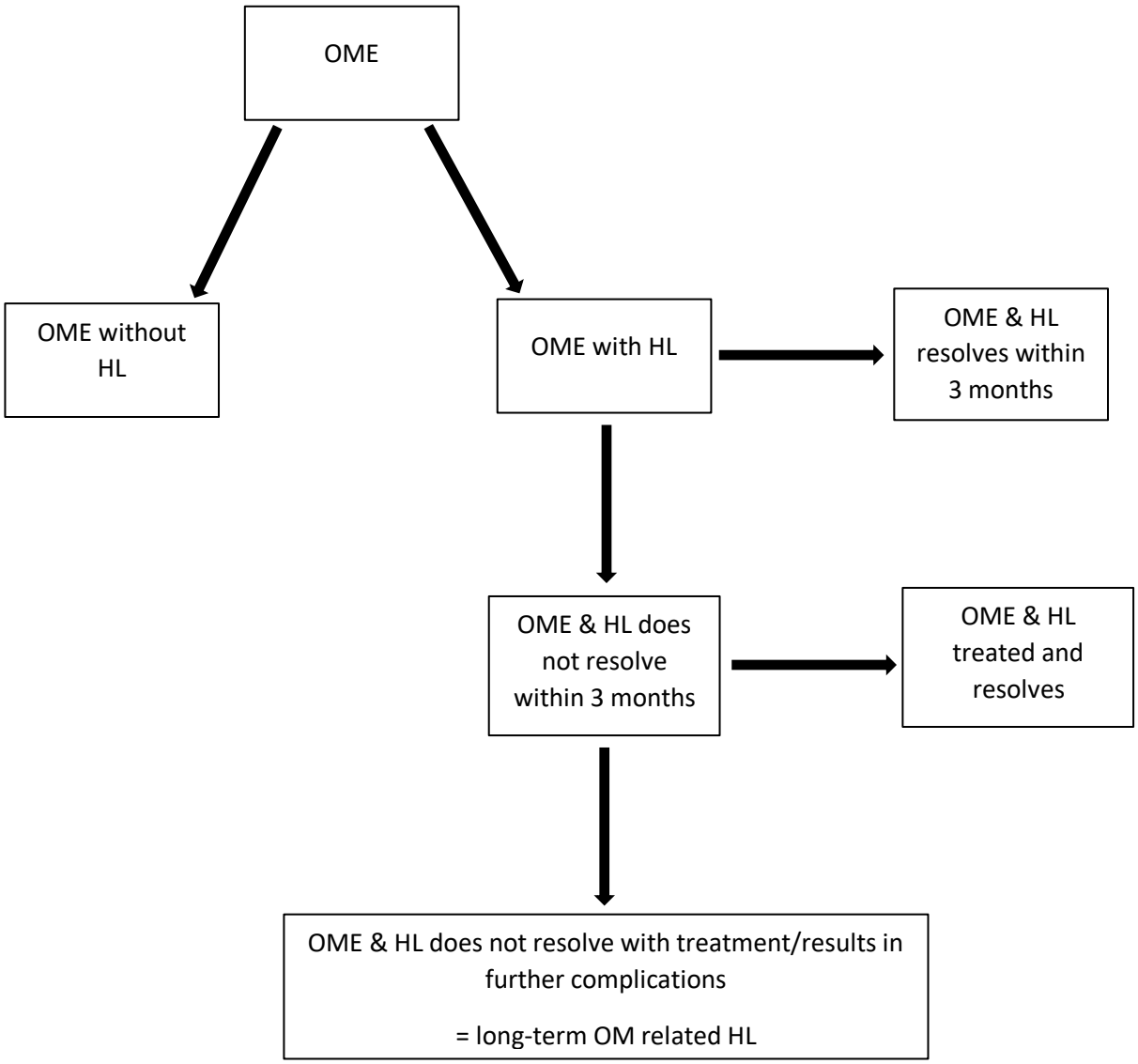


Figure 2.1 Classification of long-term OM related HL

lives with consequences that continue into adulthood (Wijlaars et al., 2016). The Department of Health & Social Care defines a long-term condition as “one that cannot currently be cured but can be controlled with the use of medication and/or other therapies” (Department of Health & Social Care, 2015). Contemplating on this in relation to OME and how it is clinically monitored, these definitions of a long-term/chronic condition apply to children for whom OME and HL does not resolve or results in further complications as presented in Figure 2.1 which displays when OME and HL can be classed as a long-term condition.

This thesis argues for the classification of OME and associated HL that is experienced beyond the typical clinically defined window of resolution period of 3 months and after the initial set of treatment, as a long-term condition; as after this point it is difficult to pinpoint the resolution of the condition.

Due to the nature of OME and its potential treatment complications, long-term or chronic OM would generally refer to OME (NICE, 2016). AOM may also contribute, if it is recurrent. Although the usual case is for OME to develop after AOM infection clears, children experiencing long-term OME are more prone to developing AOM (Berkman et al., 2013). Hence, recurrent AOM in most cases may be a complication of OME. On the basis of all that has been discussed above, this thesis addresses children who are experiencing OME associated HL either as a result of the middle ear fluid itself or complications of OME, or its treatment, for over 3 months as having a long-term condition termed as long-term OM related HL.

2.3.1 Mechanisms of impact

Referring back to the definition of a long-term or chronic health condition put forward by Wijlaars et al. (2016), the definition states that a long-term health condition may affect children's lives with consequences that continue into adulthood. As mentioned earlier, long-term HL has the potential to develop alongside chronic OM. This HL may differ from a permanent SNHL due to its fluctuating nature. However, as it is widely known that permanent childhood SNHL impacts development, a long-term HL associated with OM may also have similar effects due to its chronic nature and lack of support in place for these children as their HL is not seen as a typical permanent HL. The following text introduces the arguments for exploring the impact that long-term OM related HL may have on development.

2.3.1.1 Sensitive periods

It is well established that permanent HL in childhood can greatly hinder areas of development such as speech, language, behaviour, cognitive and social development (Brennan-Jones et al., 2014; Su and Chan, 2017; Sininger et al., 2010). Its impact on spoken language and communication is most significant, yet early identification and intervention can aid the development of age-appropriate spoken language (Davis et al., 2009; Yoshinaga-Itano et al., 1998; Yoshinaga-Itano, 1999; Downs and Yoshinaga-Itano, 1999). If the childhood HL remains with no intervention or delays in intervention, it can have long-term effects on a child's development into adolescence and adulthood – affecting their literacy, educational success and quality of life (van Eldik et al., 2004; Stacey et al., 2006; Worsfold et al., 2018; Idstad et al., 2019; van der Straaten et al., 2020). Furthermore, studies have also reported effects on children's psychosocial development, where they have reduced social skills and are at an increased risk of mental health issues (Hindley et al., 1994; van Eldik et al., 2004; Stevenson et al., 2018; Idstad et al., 2019; van der Straaten et al., 2020).

What is not known however, is whether experiencing CHL during childhood for long periods of time has similar effects on development. The peak prevalence of OM is during early childhood where much of the foundations of development are set down. Sensitive periods of development are limited periods in development where the effects of experience on the brain are unusually strong (Knudsen, 2004). Sensitive periods occur during childhood and are periods of time in which the developing child is particularly receptive to experience or particularly hindered by the absence of certain forms of experience (Sylva, 1997). These periods may last from months to years during which absence of auditory stimuli may influence development. For example, the sensitive period for speech and language development is suggested to be up until 3 years of age (Pillai et al., 2017). OME is most prevalent between the ages of 1-3 years so any HL present with the condition may influence speech and language development e.g. children may present with a delay in speech and language ability (Zielhuis et al., 1990; Casselbrant et al., 1985; Pillai et al., 2017).

Nevertheless, although more difficult to occur, changes in neural pathways can occur beyond sensitive periods (Knudsen, 2004). Therefore, children who experience temporary HL associated with OME during childhood may not miss the window for development and thus it may be thought that these children are be able to "catch up" on development once the HL has subsided. The issue may remain however, when OME and related HL persists or recurs during childhood and children do not have this opportunity with an optimum auditory experience. Yet, it is not known what impact long-term OM related HL may have on development as most research has focused on OME of a shorter nature or has focused on the effects of the middle ear effusion as opposed to any HL present.

Research has shown that the implications of permanent congenital childhood HL are seen when HL is identified beyond 6-9 months of age (Brennan-Jones et al., 2014; Pimperton et al., 2017). Most cases of OME in children arise and hence are identified beyond this age, with children having to undergo a 3-month period of watchful waiting to determine whether it is persistent or causing hearing loss. As

such, it is not known how many and which children will go on to develop persistent OME and HL and there may be concern for these children if their HL has the potential to result in implications to their development. It is therefore really pressing that we seek to investigate whether long-term OM related HL has any impact on child development in order to provide these children with the appropriate information and support when a child first presents with OM and HL. The following section outlines in more detail how long-term OM related HL may influence development.

2.3.1.2 Biological mechanisms

Although the hearing impairment associated with OME relates to the impaired functioning of the middle ear and hence the peripheral auditory system, changes to the central auditory system as a result of CHL related to OME have been reported by both animal and human behavioural studies (Moore, 1985; Moore et al., 1991; Moore et al., 1999; Hogan and Moore, 2003). These studies report that the CHL associated with OME leads to impairment in binaural hearing, which persists even after resolution of HL. Binaural hearing refers to binaural processing of stimuli presented to both ears in the central auditory system and is important in the processes of segregating sounds in noisy environments and in localisation of sound (Moore et al., 2001; Musiek and Chermak, 2015).

Difficulties with binaural hearing can present as difficulties in listening in background noise as well as tuning in and identifying where sounds are coming from. Therefore, children with ongoing CHL as a result of long-term OME may experience these difficulties. Furthermore, asymmetric CHL has especially been found to influence binaural hearing (McCullagh and Bamiou, 2014). As OME related HL is often asymmetric, the effects would be greater than with symmetric HL. The main issue presents with detecting speech in noise (Musiek and Chermak, 2015).

Having said this, animal studies have shown that these effects of CHL can be reversed once hearing levels return to normal (Knudsen et al., 1984; Moore et al., 1999). Nevertheless, in the case of long-term OME, hearing levels may not reach normal levels or may fluctuate, and children may continually experience these difficulties in hearing. This continual reduction of auditory signals during early development may result in a reduced ability to perceive and produce intelligible speech, which is key for spoken communication (Sininger et al., 2010). Furthermore, the fluctuating nature of HL that may accompany OME, may lead to inconsistencies in the auditory signal (Whitton and Polley, 2011). This may lead to children presenting with difficulties in communication and hence language and social functioning which may ultimately impact other areas such as academic ability and educational attainment (Brennan-Jones et al., 2014; Su and Chan, 2017).

Additionally, other factors that may add to the inconvenience of long-term OM include ongoing ear infections and pain/discharge as well as missing school to attend multiple hospital or doctors' appointments. For children fitted with hearing aids in particular, due to the fluctuating nature of the HL, these would have to be re-fitted constantly (Samra, 2018). Accordingly, there is reason to hypothesise that long-term OM related HL may influence development, and to investigate this further.

2.3.2 Summary

OME is a prevalent condition in childhood that may result in a child presenting with a temporary mild to moderate HL. While commonly temporary, in a smaller proportion of cases the condition may be recurrent and long-term, potentially leading to HL lasting for a longer period which can span from months to years. As permanent HL is known to impact development, it is important to investigate the prevalence of long-term OM related HL as it not known how many children are affected by this as well as the potential impact this may have on child development. The following

sections review the literature of OM related HL epidemiology and its impact, in order to identify gaps in knowledge to inform further research.

2.4 Epidemiology of (OM related) conductive hearing loss in children

2.4.1 Overview

OME is often indicated by the presence of middle ear fluid. Hearing levels are generally not assessed unless parents report issues with the child's behaviour, language development or performance at school (Williamson, 2007). This makes it difficult to estimate the prevalence of OME related HL. There are limited population data on the prevalence of OME related HL as many studies when measuring OME have not assessed hearing levels and have made diagnoses based on otoscopic and tympanometric findings. It is therefore not known how common OM related HL is in the general population. This is something that needs to be addressed.

2.4.2 Epidemiology of HL in children in population studies

Of the research that exists, estimates of OM related HL generally come from small cross-sectional studies. While these are insightful, cross-sectional studies only provide an estimate of HL at one point in time and the smaller prospective cohort studies lack external validity due to lack of generalisability to the greater population. Population studies which have studied OM related HL are lacking. Furthermore, most estimates of childhood HL in general from population studies are limited to permanent hearing losses >40dB HL and do not include estimates of temporary or unilateral losses. However, there are some longitudinal and cross-sectional studies that have included children

with mild to moderate hearing losses. By looking at the proportion of children reported to have mild-moderate degrees of HL, we can get an idea of the proportion of children who may have OM related HL, that is if studies are not specific to children with SNHL. Cross-sectional studies of HL in children aged between 4-19 years report estimates of HL ranging from 5 to 7% (Sheridan, 1972; Dodgeon and Shepherd, 2014; Feder et al., 2017; Avnstorp et al., 2016; Ayukawa et al., 2004; Oyewumi and Adejumo, 2011; Czechowicz et al., 2010). However, many of these are small studies and do not give age specific estimates. In order to study the prevalence of OM related HL for more persistent cases of OM, data from large longitudinal population studies are required which measure both the presence of OME and hearing levels.

Table 2.2 summarises existing population studies from which OM related HL estimates may be obtained along with their limitations. This is a collation of all large national population studies which have studied childhood HL providing either cross-sectional or longitudinal estimates to compare and contrast the available data on hearing.

Studies listed at the top of the table are specific to OM and OM related HL. Studies which follow provide general estimates of childhood HL which are not limited to SNHL. As can be seen the limitations with these studies include estimating prevalence of OME without measuring hearing levels, using parent reported data and only taking estimates at one point in time. The NHANES studies found that most of the HL experienced by 6-19-year olds was mild-moderate in degree, as opposed to severe-profound. We cannot be certain, however of the proportion of these hearing losses that are accounted for by CHL. Furthermore, cross-sectional studies are not the best suited to study OM related HL due to fluctuations in hearing levels. From these population cohorts that are in existence, it is difficult to draw conclusions on the prevalence of long-term OM related HL due to issues with their design.

Table 2.2 Summary of population studies providing estimates of childhood HL

Population study	Country	Study design/nature of estimate	N	Target population	Sample	Measure of OM/hearing	Findings	Limitations
1970s British Birth Cohort Study (BCS70) Bennett and Haggard (1999)	UK	Cumulative estimates of middle ear disease and hearing difficulty at age 5 years	~12,000	All UK (England, Scotland & Wales) births between 5 and 11 April 1970	Children with data on hearing and middle ear disease up to 5 years	Parental reports of suspected or confirmed hearing problems and purulent (non-wax) ear discharge up to the age of 4 as well as between ages 4 and 5	Prevalence of middle ear disease at 5 years was estimated to be 11.5% for ear discharge and 8.4% for hearing difficulty	Data were obtained through parent report thus may not be reliable estimates of OM and OM related HL. Middle ear disease not specific to OME.
Dunedin Multidisciplinary Health and Development study Silva et al. (1986)	New Zealand	Cross-sectional estimate of OME at age 5	853	A one-year birth cohort of children born in Dunedin City, New Zealand between 1 April 1972 and 31 March 1973.	Two groups from the main sample: those with bilateral OME at age 5 and those who were otologically normal at age 5	Tympanometry and otomicroscopy	123 children had either unilateral or bilateral OME at age 5, giving a prevalence rate of 14.4%	OME was examined using tympanometry at age 5 with no report on hearing levels. Reported prevalence at 5 years only
Dunedin Multidisciplinary Health and Development study	New Zealand	Longitudinal – estimates of middle ear fluid at ages 5, 7, 9 & 11	962	A one-year birth cohort of children born in Dunedin	Children with data on middle ear status over the period of 5	Tympanometry, otomicroscopy and audiometry	At age 5, 8.8% had evidence of middle ear fluid, at age 7, 6.1% of children had evidence of	Although this study reported that 5.5% of children had proven HL

Bennett et al. (2001)		Cumulative incidence of OME related HL between 5 and 9 years		City, New Zealand between 1 April 1972 and 31 March 1973.	years to 9 years		middle ear fluid, at age 9, 1.8% had evidence of middle ear fluid and at age 11, 1.6% had evidence of middle ear fluid. It was also reported that 5.5% of children had proven HL and had received more than one set of grommets for both ears between 5 and 9 years. 4.7% of children had bilateral persistent OME but without evidence of HL on at least one occasion. Furthermore, 2.7% had unilateral OME on at least one occasion	between ages 5 and 9 years, hearing levels were not reported for each age in order to study HL prevalence rates
Avon Longitudinal Study of Parents and Children Midgley et al. (2000)	UK	Longitudinal – estimates of OME without HL at 8 months, 12 months, 18 months, 25 months, 31	1,400	Children born in Avon in Bristol, UK between 1 April 1991 and 31 December 1992	A randomly selected 10% of the cohort from the last 7 months of the cohort (births between June	Tympanometry	Prevalence of OME decreased with age with 36.6% of children having bilateral OME at 8 months, 14.1% at 43 months and	OME was examined using tympanometry with no measure of hearing levels

		months, 37 months, 43 months, 49 months and 61 months			1992 and December 1992) whose middle ear function was assessed during the first 5 years of life		10.5% at 61 months	
Apostolopoulos et al. (1998)	Greece	Cross-sectional estimate of OME in 6-12 year olds	5,121	Children attending elementary school (6-12 year olds) in Argolida, Greece between May and October 1996	Children who had received an otolaryngological examination	Pneumatic otoscopy, tuning fork tests, tympanogram, acoustic reflex test and audiometry	Point prevalence of OME was 6.5%. 86% of children with OME had HL >25dB	Cross-sectional estimate of OME and HL. OME and hearing levels were not reported for each age in order to study HL prevalence rates
Danish National Birth Cohort Todberg et al. (2014)	Denmark	Cumulative incidence of OM between 6 months and 7 years	54,772	Children aged 0-7 years born between 1996 and 2003 in Denmark	Children whose parents were interviewed regarding OM at 6 months, 18 months and 7 years	Parental report of middle ear infections and ventilation tube insertion	Cumulative incidence of OM at 7 years was 60.6%. Four or more episodes of OM were reported by 0.3%, 13.6% and 23.9% of children at 6 months, 18 months, and 7 years	Parental report of middle ear infections so may not be reliable. Also, not specific to OME. No measure of child's hearing
Western Australian	Australia	Cross-sectional estimate of OM	1,344	Children born at (2^{nd} generatio	2nd Generation Raine Study	Tympanometry and audiometry	Prevalence of bilateral OM related HL was	Represents the prevalence of OM related HL

Pregnancy Cohort study Brennan-Jones et al. (2020)		related HL in 5 to 7-year olds		n (Gen2) Raine Study participants) King Edward Memorial Hospital in Perth, Australia between 1989 and 1991.	participants who completed tympanometry and audiometry assessment at 5 to 7 years of age.		2.1% in five to seven-year-old children	at one point in time only
Genetico-epidemiological survey of population of Sichuan, China Liu et al. (2001)	China	Cross sectional estimate of HL in children aged 15 years and under	34,157	Children in Sichuan, China attending the selected referral sites across Sichuan to represent the whole population of Sichuan.	Children with audiometric data	Audiometry	Prevalence of HL was 0.67% for children aged 15 years and under. 54.19% of HL was OM related	Cross-sectional estimate of HL. Represents the prevalence of OM related HL at one time point only
Millennium Cohort Study Butcher (2020)	UK	Longitudinal – estimates of OME without HL at 9 months, 3 years, 5 years, 7 years, 11 years and 14 years and estimates of HL including but not limited to OME at each age	7,470	Children born in the UK between 1 September 2000 and 31 August 2001 (for England and Wales), or between 24 November 2000 and 11 January 2002 (for Scotland	Children with hearing data at all time points	Parent report of child's hearing	Prevalence of OME without HL was estimated to be 1.7%, 1.9%, 2.1% and 1.2 % at 3 years, 5 years, 7 years and 11 years, respectively Prevalence of HL was 12.2%, 2.0%, 5.3%, 6.3%, 4.7% and 3.9% at 9 months, 3 years, 5	HL prevalence rates are not just limited to OME and data were parent reported (self-reported at 14 years). No data on type or degree of HL to distinguish likely OM related HL

				and Northern Ireland) and resident in the UK at 9 months			years, 7 years, 11 years and 14 years	
Longitudinal Study of Australian Children Yiengprugsawan et al. (2013)	Australia	Longitudinal – estimates of HL at ages 6/7 years, 8/9 years and 10/11 years.	2 cohorts: B cohort - 5,107 K cohort - 4,983	Children born between March 1999 and February 2000 (aged 4–5 year = K cohort) and those born between March 2003 and February 2004 (aged 0–1 year = B cohort).	Children with hearing data at any of the time points	Parental report of ear infections and hearing problems at 6/7 years for the B cohort and 8/9 years and 10/11 years for the K cohort	Prevalence of HL in non-Indigenous Australian children aged 6/7 years in the Longitudinal Study of Australian children was 2.8%. Prevalence at ages 8/9 and 10/11 were 2.5% and 2.1%, respectively. The prevalence of HL for Indigenous children who are a population more prone to OM, at these ages were higher. They were 4.8%, 4.0% and 2.5% at 6/7 years, 8/9 years and 10/11 years, respectively	Data on HL were parent reported and not limited to OM. No information on cause, duration, and severity of hearing problems
1946 Birth Cohort Study (National Survey	UK	Longitudinal – estimate of cumulative incidence of HL	5,362	A socially stratified sample of 5,362	Children with hearing data available from	Parent and doctor reports of HL from birth to 15 years	Cumulative incidence of 0.5% for HL between birth and 15 years	Data obtained from parent and doctor interviews

of Health and Development)		from birth to 15 years		singleton babies from 13,687 of all births recorded in England, Scotland and Wales during one week of March 1946, born to married parents selected for follow-up	birth up to 15 years			
1958 Birth Cohort Study (National Child Development Study) Sheridan (1972)	UK	Cross-sectional estimate of HL at 7 years	11,276	Children born in England, Wales, and Scotland, during 1 week in 1958	Children with hearing data at 7 years	Pure-tone audiograms and results of clinical hearing tests at age 7	Prevalence of HL at 7 years was 5.64% Prevalence of HL at 16 years was 4.4%	Cross-sectional estimate of HL not limited to OM. HL defined as significant auditory impairment categorised as moderate, serious or severe, thus may not include mild HL associated with OM
1970 British Birth Cohort Study (BCS70)	UK	Cross-sectional estimate of	14,903	All UK (England, Scotland &	Children with audiometric	Audiometry	7% of children had bilateral HL	Cross-sectional estimate of HL,

Dodgeon and Shepherd (2014)		bilateral HL at 10 years		Wales) births between 5 and 11 April 1970	data at 10 years			no report on OM related HL.
US National Health and Nutrition Examination Survey (NHANES) Niskar et al. (1998)	USA	Cross-sectional estimate of HL for 6-19-year olds during 1988-1994	6,166	Individuals representative of the US civilian non-institutionalized population 2 months of age or older during 1988-1994	6-19-year olds with audiometric hearing data during 1988-1994	Self-reported hearing status and audiometry	Prevalence rates for any hearing loss >15dB for 6-19-year olds during 1988-1994 was 14.9%	Cross-sectional estimate of HL, no report on OM related HL.
US National Health and Nutrition Examination Survey (NHANES) Shargorodsky et al. (2010)	USA	Cross-sectional estimate of HL for 12-19-year olds during 2005-2006	1,771	Individuals representative of the US civilian non-institutionalized population 2 months of age or older during 2005-2006	12-19 year olds with audiometric hearing data during 2005-2006	Audiometry	Prevalence rates for any hearing loss >15dB for 12-19-year olds during 2005-2006 was 19.5%	Cross-sectional estimate of HL, no report on OM related HL.
US National Health and Nutrition Examination Survey (NHANES) Su and Chan (2017)	USA	Cross-sectional estimates of HL for 12-19-year olds during 2007-2008 and 2009-2010	2007-2008 = 1,238 2009-2010 = 1,339	Individuals representative of the US civilian non-institutionalized population 2 months of age or older during 2007-2008 and 2009-2010	12-19 year olds with audiometric hearing data during 2007-2008 and 2009-2010	Audiometry	Prevalence rates for any hearing loss >15dB for 12-19-year olds during 2007-2008 was 22.5% and during 2009-2010 was 15.2%	Cross-sectional estimate of HL, no report on OM related HL.

Canadian Health Measures Survey Feder et al. (2017)	Canada	Cross-sectional estimate of HL for 6-19 year olds	1,879	Canadian individuals living in these 5 regions: Atlantic, Quebec, Ontaria, Prairies and British Columbia	6-19-year olds with audiometric data	Audiometry	Prevalence of HL was 7.7% for 6-19 year olds	Cross-sectional estimate of HL, no report on OM related HL
Hussain et al. (2011)	Pakistan	Cross-sectional estimate of HL in 5-15 year olds	5,120	Children aged 5-15 years, attending one of 170 schools in Karachi, Pakistan during 2008-2009	5-15 year old school children with audiometric data	Audiometry	Prevalence of HL >25 dB in 5-15 year olds was 13.6%. 88.2% of these children has conductive HL, mainly due to impacted wax.	Cross-sectional estimate of HL, no report of conductive HL related to OME.
Fitzpatrick et al. (2020)	Canada	Cross-sectional estimate of HL in 4-9 year olds	644	Canadian children resident in and attending schools in Nunuvat	4-9 year olds attending one of six selected schools in Nunuvat with audiometric data	Audiometry	Prevalence of any HL ≥30dB for 4-9 year olds was 19.3%.	Cross-sectional estimate of HL, no report on OM related HL.

2.4.3 Gaps in knowledge

While there are many epidemiological studies of childhood HL, studies focusing specifically on OM related conductive HL are sparse, thereby leaving the prevalence of long-term OM related HL unknown. The few studies which have estimated the prevalence of OM or OM related HL have used parent or self-reported measures or have used standardised measures to provide cumulative or cross-sectional estimates. As mentioned, hearing levels with OM can fluctuate, thus taking hearing measures at one point in time may mean that estimates are not reliable. This means that studies which have taken valid measures of hearing at more than one time point are required.

Furthermore, to estimate prevalence of long-term OM related HL, longitudinal studies which have assessed OM and hearing at a range of time points throughout childhood are needed. These studies will also be useful to compare prevalence rates at different ages. There is a clear need for longitudinal studies which have used valid, reliable prospective measures of OM and hearing that are not subject to recall bias.

Uncovering the prevalence of long-term OM related HL is important in order to determine how common the condition is and in turn to identify whether these children require support in managing and living with their HL. The remaining sections of this chapter review how long-term OM related HL may influence development.

2.5 Hearing loss and child development

HL of any nature and degree has the potential to influence communication skills due to difficulties in hearing speech sounds, particularly in background noise (Turner and Per-Lee, 1990; Peterson, 2017; Wendt et al., 2017). A child's ability to hear language in their auditory environment can be restricted

by HL and as a consequence have a negative impact on language acquisition (Shojaei et al., 2016). This in turn may impact their cognitive ability and ability to learn in school as well as to participate in social interactions (Shojaei et al., 2016). As mentioned earlier, studies have found that even a mild CHL can particularly influence binaural hearing which has implications for hearing and processing speech sounds and hence, developing language and communication skills. Therefore, CHL associated with long-term OM may also present with implications to a child's development, particularly in regard to social and cognitive development. Many developmental theories emphasise the role of learning and cognition and social functioning in development (Piaget, 1950; Vygotsky, 1978; Halford, 1999; Case, 1985; Case and Bruchkowsky, 1992; Brand, 1996; Jensen, 1998; Sternberg, 1999b; Ackerman et al., 2003; Ceci et al., 1990; Erikson, 1950). These theories offer insight into the interrelationships between the different areas of development. Cognitive developmental theories highlight the importance of social functioning in learning and cognition and vice versa, psychosocial development occurs through what is learnt through exploration of the environment and through the influence of a child's past experiences and their knowledge and abilities. As HL has the potential to influence both cognitive and social abilities, implications to each individual domain may thus affect the other. For instance, issues during one stage of development that may occur due to HL may hinder success in further stages, as proposed by Erikson in his psychosocial theory of development (Erikson, 1950; Orenstein and Lewis, 2020). As social behaviour is key to cognitive development and learning, these areas may also potentially be hindered. The common theme of development occurring through interaction proposed by these theories provides the framework for the work presented in this thesis on how long-term OM related HL may impact psychosocial and cognitive development. The next sections explore how HL may influence these areas of development as informed by these theories.

2.6 Implications of childhood hearing loss on psychosocial development

This section discusses the potential effects of HL on psychosocial development and mental health and informs the research questions presented in Chapter 3.

As outlined in Erikson's theory (Erikson, 1950; Orenstein and Lewis, 2020), a lot of the earlier stages of psychosocial development involve children exploring the world around them. This involves interaction and communication with others, for which hearing is key. While it is known that HL in childhood can interfere with speech and language development, and thus present with social challenges, there is less known about its impact on psychosocial development and mental health. HL may act as a barrier to communication mainly through poor development of functional speech and language skills which may in turn result in challenges at each stage of development as proposed in Erikson's theory e.g. making it difficult to engage in age-appropriate activities (National Research Council, 2005). According to Erikson's theory, difficulty or failure at each stage which may be influenced by HL can lead to feelings of inadequacy which can contribute to poorer psychosocial functioning.

It can thereby be argued that childhood HL may impact psychosocial development at any of the earlier stages. For example, during the first stage of development children build trust in their caregiver and environment in general, as a result of their needs being met through interaction with their caregiver. For children with HL, this may not be consistent if the child is unaware of the auditory stimulation that their caregiver is using to comfort them or show affection (Rall, 2007). The child may also not be aware of auditory cues (such as a ringing telephone or doorbell) which indicate that their caregiver's attention is elsewhere. Furthermore, some parents may be experiencing distress over their child's HL and thus may not be as responsive (Rall, 2007).

The second stage of psychosocial development is about developing autonomy. Children with HL may not be as free to explore their environment and may be overprotected and lack encouragement to

try new activities and exercise their independence. As a result, they may end up feeling helpless and shameful about their abilities (Berger, 2003; Rall, 2007). This will influence them in the third stage where children begin to assert themselves in play and interaction. Here, children with HL may lack the confidence to interact with other children and initiate play. The environments in which they can explore and communicate with others may also be limited (Rall, 2007). If they are restricted in this way, this may also apply to the fourth stage where children are keen to master challenges. Failure to accomplish social and intellectual challenges may lead to a lack of confidence and doubt in their abilities (Orenstein and Lewis, 2020). At this stage and the next, interaction with peers becomes of more importance (Orenstein and Lewis, 2020). During adolescence, there is the pressure of not only fitting in with peers but also in deciding what path life will take in terms of education and career (Steinberg and Monahan, 2007). Lack of confidence and doubt developed from earlier stages, as well as hearing problems at this point which may add to this, may hinder development at this stage (Chávez, 2016). Furthermore, if rejection from others due to stigma of HL occurs, this may lead to feelings of loneliness and inadequacy, not allowing the young person to develop their identity and therefore also affecting the adulthood stages (Mushtaq et al., 2014; Orenstein and Lewis, 2020).

With interaction and communication being key to development and language being the main mode of communication, issues with language development and understanding resulting from HL may influence psychosocial development. Children may not present with the confidence to interact with others if they feel inadequate in their ability to talk and communicate, especially if they have negative past experiences with interaction, as past experiences influence levels of motivation in any given situation and determine the opportunities that children (and adults) have to develop certain abilities and expertise (Ackerman et al., 2003). Potential consequences resulting from this include poor mental health relating to anxiety and depression. This is discussed further below.

2.6.1.1 Mental health

The term 'psychosocial' covers the influence of social factors on mental health and behaviour, suggesting that poor social development may negatively influence mental health and behaviour (Vizzotto et al., 2013). Positive outcomes at each of Erikson's proposed stages promote the development of a stable foundation for core belief systems in relating to the self and outer world. On the other hand, negative outcomes may hinder this development and result in children having poor beliefs relating to themselves and the world around them (Knight, 2017). These maladaptive tendencies have the potential to present as low self-esteem and self-doubt in their abilities, representing feelings of insecurity. This is particularly concerning as low self-esteem has been found to be strongly correlated with poorer mental health, leading to a predisposition of internalising/emotional disorders such as depression and anxiety (Greenberg et al., 1992a; Orth et al., 2008; Roberts and Monroe, 1992; Mushtaq et al., 2014; Keane and Loades, 2017). Furthermore, continuity of psychosocial difficulties from preschool years into middle childhood and adolescence can occur. This suggests that negative outcomes at each of Erikson's stages may contribute to poor mental health across the life course which in turn underlines the importance of early intervention for overall well-being and mental health (Luby et al., 2014).

It has been reported that 1 in 10 children and young people under the age of 16 in the UK experience a mental health disorder (Murphy and Fonagy, 2012). Emotional disorders including anxiety and depression are amongst the most commonly reported problems and the prevalence of mental health issues in children and young people has been seen to rise overtime with one in twelve 5 to 19-year olds experiencing an emotional disorder in 2017 (Murphy and Fonagy, 2012; NHS Digital, 2018). The World Health Organisation (WHO) reports that mental health conditions are major causes of illness and disability among young people with consequences of not addressing psychosocial development and mental health in childhood extending into adulthood (WHO, 2020).

The distress caused by mental health issues in childhood and adolescence can impact on educational attainment and social relationships and can also affect physical health and life chances (Murphy and Fonagy, 2012). Furthermore, it has been reported that over 50% of mental health issues in adult life start before age 15 (Murphy and Fonagy, 2012). The implications of mental health issues are wide-ranging across the life course and hence the importance of identifying and supporting children with an increased risk of developing mental health issues is further highlighted.

As mentioned earlier, the outcomes at each stage of development may influence mental health with negative outcomes relating to feelings of inadequacy, and low self-esteem being linked to poorer mental health states through experiencing depression and anxiety. As HL may potentially interfere with virtue development at each stage, it is possible that children with HL may be at greater risk of developing mental health issues through poorer psychosocial development.

As defined by the World Health Organisation (WHO), mental health is:

> A state of well-being in which an individual realises his or her own abilities, can cope with the normal stresses of life, can work productively, and is able to make a contribution to his or her community. (World Health Organisation, 2018)

Although WHO recognise that mental health is not merely the absence of mental health disorders, this definition is said to have a few limitations in highlighting positive feelings and positive functioning as essential factors for mental health (Galderisi et al., 2017). Galderisi et al. (2017) propose mental health as being a dynamic state of internal equilibrium which enables individuals to use their abilities in harmony with universal values of society for which basic cognitive and social skills are required due to their impact on everyday life. These include the ability to pay attention, remember and organise information, solve problems, make decisions, and use one's own set of verbal/non-verbal abilities to communicate and interact with others (Galderisi et al., 2017). If these abilities are hindered as may be the case in children with HL, particularly regarding verbal communication ability; this may potentially influence mental health if as a result, children are deficient in social interaction. Furthermore, research has shown that the quantity and quality of an

individual's social relationships are associated with better mental health across the life-course (Berkman and Glass, 2000; Cohen, 2004; George, 1989). Therefore, children with HL who exhibit communication difficulties may be at an increased risk of developing mental health issues. Accordingly, it is important that the mental health of children with long-term OM related HL is considered.

The next section discusses findings from the literature on the psychosocial functioning and mental health of children with HL.

2.6.2 Children with permanent childhood hearing loss

The literature provides evidence that children with permanent hearing impairment experience psychosocial problems and mental health issues to a greater degree than normally hearing children (Stevenson et al., 2015). Hearing impairment in children and adolescents has been associated with a range of mental health issues including depression, aggression, oppositional defiant disorder and conduct disorder, hyperactivity, anxiety, somatization and delinquency (Stevenson et al., 2015; Theunissen et al., 2014). One study on college students with disabilities including hearing impairment found that the positive or negative tendencies developed as proposed in Erikson's stages were significant contributing factors for the mental health condition of the students, suggesting that positive psychosocial development in students with disabilities is linked to better mental health (Chen, 2019).

Interestingly, there has been some inconsistency in the level of impact that HL has on psychosocial development which has been reported to potentially be due to the degree of HL studied (Moeller, 2007). While it may be thought that children with greater degrees of HL would have poorer psychosocial functioning compared to children with milder degrees of HL, it has been shown that

children with milder degrees of HL also exhibit emotional/behavioural problems, poorer mental health and poorer self-esteem and thus experience poorer psychosocial related quality of life (Wake et al., 2004).

In addition, studies comparing the psychosocial development of children fitted with cochlear implants with children fitted with standard hearing aids have reported that children fitted with cochlear implants showed better psychosocial functioning than children with hearing aids (Theunissen et al., 2015; Wong et al., 2017). Children with cochlear implants were found to have similar psychosocial functioning to normally hearing peers, however children with hearing aids were found to have significantly higher levels of psychopathological symptoms (pertaining to depression, generalised and social anxiety, somatisation and obsessive compulsive disorder) than both children with normal hearing and cochlear implants (Theunissen et al., 2015). The difference was reported to be as a result of the intensity of the rehabilitation programme. Furthermore, it was reported that psychosocial problems may arise in children who develop good language ability with the help of a hearing aid or cochlear implant but who still experience difficulties with listening and communicating in everyday environments, with age at hearing intervention, severity of HL and communication mode not being associated with psychosocial outcomes (Wong et al., 2017).

Moreover, a study focusing specifically on children with mild to severe HL found that these children exhibited more psychosocial problems (relating to emotional problems, behaviour problems and social skills) than children without HL, with better psychosocial functioning being predicted by female gender and early identification and intervention and not vocabulary and degree of HL (Laugen et al., 2016). The findings from these studies suggest that without timely identification and appropriate intervention, even milder degrees of HL have a significant impact on psychosocial development in relation to social skills and internalising symptoms such as depression and anxiety. As mild HL associated with OM is usually detected later in childhood and with children undergoing a

waiting period for natural resolution of OM, children who develop OM related HL may therefore be susceptible to poorer psychosocial functioning.

2.6.3 Children with OM related hearing loss

Primary evidence for the impact of childhood HL on psychosocial functioning comes from studies on permanent childhood HL. While conductive OM related HL may differ from permanent HL in its fluctuating, asymmetric nature, there is some evidence from a range of studies that OME related HL may also have a negative impact on psychosocial development.

Higher levels of emotional symptoms/internalising behaviours were observed in later childhood (4-8 years) in children with a history of OME & HL for both acute and persistent cases than children in control groups (Timmerman et al., 2007; Gouma et al., 2011). Additionally, Vernon-Feagans et al. (1996) reported that children with chronic OME who attended day care were observed to be playing alone a lot more than those without OME. Scores for social skills were also found to be lower in adolescents with a history of OME compared to those without OME history (Stenton, 2007). However, although Gouma et al. (2011) reported poorer psychosocial functioning two years after children had experienced OME, which supports a potential lasting effect on development, these studies were cross-sectional studies, from which we cannot infer any influence over time. What is unknown is whether these effects are long lasting throughout childhood, or whether the effect is attenuated over time. There is a need for prospective longitudinal studies to answer this question.

Longitudinal prospective studies looking at the impact of OM related HL on psychosocial development are limited and generally have focused on attention related behaviour. Although the case control studies by Timmerman et al. (2007) and Gouma et al. (2011) were cross-sectional and did not take account of confounding factors including socioeconomic status, a longitudinal cohort

study by Hogan et al. (2014) which took place over 6 years and did account for socioeconomic status reported a negative association between ongoing ear infections and hearing problems at ages 4/5 years and emotional symptoms at 10/11 years. Hearing problems at 0/1 years were also associated with emotional distress symptoms at 6/7 years. Nonetheless, this study was not specific to OM and further prospective studies are required to support this finding.

A randomised controlled trial for early vs late ventilation tube insertion in children with middle ear effusion did not find a significant difference in scores for outcomes between groups at a range of ages during childhood, suggesting that OM does not have any lasting impairments on psychosocial functioning (Paradise et al., 2001b; Paradise et al., 2003a; Paradise et al., 2005; Paradise et al., 2007) . However, these children were selected based on the presence of middle ear effusion and not HL, therefore children may not have had HL. Furthermore, most children in the late treatment group still received intervention which may have counteracted any impact that lasting OM related HL would have. Hence, findings from this study are not reliable.

A study by Bidadi et al. (2008) however, found that scores for social skills of 15-30-year olds were lower in those with HL associated with chronic OM than in control cases. Although a case control study, this study looked at individuals with OM since childhood and into adulthood. As findings showed social skills to be impacted even at these ages, they illustrate that the impact of long-term OM related HL on social development may be long lasting and could have significant implications for psychosocial development. Having said this, as a cross-sectional case control study, we cannot be certain that the findings are due solely to OM related HL as other factors such as personality may influence social skills, particularly during adulthood. It is important to assess whether these effects are consistent throughout childhood and into adulthood.

Qualitative studies enable the possible impact to be explored in more detail (Creswell, 2007). The little qualitative research that has been conducted focusing on the impact of OME and HL of a longer

nature on children has identified themes relating to social, emotional and even educational experiences.

Tierney et al. (2015) conducted a study to explore the views on daily life of living with OME and HL in children with cleft palate. They used framework analysis to analyse semi-structured interviews conducted with these children and found themes related to negative impact on emotions, educational experiences and social interactions for the child. Not only did the children struggle at school with having to sit at the front of the class and require extra support, but they also had to miss school due to appointments and ear infections. Their social interactions were negatively affected with them feeling anxious and not being able to take part in activities. This finding provides evidence of HL in children with cleft palate causing anxiety and affecting their social interactions, which according to Erikson's theory may inhibit psychosocial development.

An in-depth phenomenological study by Capewell (2014) reported similar findings in children with chronic OME without cleft palate, which suggests that chronic OME alone can have adverse effects on psychosocial development. Key themes that rose from Capewell's research were those of negative self-image and low confidence in self-advocacy. For example, children lacked the confidence to tell teachers what they needed. This represents children having low confidence and doubts about their abilities which are negative tendencies developed in the earlier stages of psychosocial development.

Furthermore, Skilton et al. (2016) conducted semi-structured interviews with adults who experienced chronic ear disease since childhood, using a content analysis approach. They found that due to stigma, participants did not disclose their hearing impairment to friends, teachers and employers which caused barriers to their education and work. This meant that they did not receive the support they needed due to fear of stigma. This highlights the importance of how chronic ear disease & HL may affect individuals throughout life as the study had the strength of studying individuals experiencing chronic ear disease since childhood. The findings show that even when they

reach adulthood, individuals with chronic ear disease and HL are still experiencing problems, representing the nature of a long-term condition.

These themes that arose in relation to social behaviour are particularly important as poor social functioning may result in poor social relationships and as mentioned earlier, social relationships have been found to be important for overall health outcomes, including mental health (Umberson and Montez, 2010). One of the mechanisms by which social relationships influence mental health is through the social support that is provided. This social support arises through social interaction (Marmot and Wilkinson, 2005). Furthermore, feelings of loneliness which have been associated with depression, are reduced (Wang et al., 2018). Children with poor social interaction have been found to have increased levels of internalising problems such as depression, anxiety and low self-concept (Strauss et al., 1986). Poor levels or poor quality of social interaction and feelings of loneliness are common in individuals with HL (Stevenson et al., 2015; Most, 2007). Experiencing this during childhood or adolescence can lead to maladaptive feelings being developed which interfere with a child's self-esteem and confidence and increase the risk of developing issues with mental health such as anxiety and depression (Greenberg et al., 1992b; Orth and Robins, 2013). Furthermore, research has shown that children with HL are at greater risk of developing mental health issues (Theunissen et al., 2014).

As indicated by the findings from the above discussed qualitative studies, social interaction is a challenging process for children and young people with OM related HL. This is not just important from a health perspective, but also in development and education as poor social functioning and internalising symptoms can have consequences for academic ability and educational attainment as well as for psychosocial functioning in later life. Recent research has shown that mental health problems predict academic performance from mid childhood and into adolescence (Agnafors et al., 2020). Data from a longitudinal cohort study were analysed to examine the relationship between mental health and academic performance during different developmental periods of childhood and

adolescence. Findings provided support for an association between internalising problems and later academic performance at each developmental stage studied (internalising problems at age 3 predicted performing below grade in English Language and Mathematics at age 12; internalising problems at age 12 were associated with incomplete grades at ages 15 and 19). However, no support was found for the effect of academic performance on internalising problems. These findings are of importance as poor academic performance may result in lower educational attainment (Magnuson et al., 2016). This effect of mental health on educational attainment relates to social selection – where mental health issues can inhibit socioeconomic attainment and even result in individuals drifting into a lower social class or never escaping poverty (Kawachi et al., 2013; Kessler et al., 2005; Miech et al., 1999).

Nonetheless, studies on adult populations have reported the inverse association where poorer educational attainment has an effect on mental health, demonstrating social causation where economic hardship increases the risk to later mental health. Explanations for higher educational attainment being linked to better mental health include additional economic resources, fewer chronic stressors, healthier lifestyles and more social support which lead to better mental health (Kessler et al., 2005; Lantz et al., 2005; Mirowsky and Ross, 2003; Ritsher et al., 2001; Schieman and Plickert, 2008; Turner et al., 1995). This therefore indicates that poorer academic performance which may lead to lower educational attainment may also pose a risk to later mental health and highlights the need to study academic achievement in children with long-term OM related HL. Additional emphasis on this need is provided as it has also been found that social and emotional learning promotes academic learning, with successful social and emotional behaviour influencing success at school as well as success in life (Zins et al., 2004). Therefore, there is a need to investigate whether HL has an impact on children through these mechanisms.

2.6.4 Gaps in knowledge

Studies have reported that HL, irrespective of its degree can have negative implications for a child's psychosocial development and mental health if not identified early enough and timely intervention not being in place. The current literature looking at the impact of OM related HL on psychosocial development mainly consists of retrospective, cross-sectional studies. While these studies provide evidence of a potential association between OM related HL and psychosocial development, prospective longitudinal studies are required in order to study whether the effects are present over time, but also to investigate the effect of long-term OM related HL overtime with HL and outcomes being measured at multiple time points.

Although limited, qualitative studies have provided further insight into the effects of OM related HL on psychosocial development. These studies have provided evidence of OM related HL having an impact on social and emotional behaviour, affecting educational experiences in children and the working lives of adults. What is not known is if this has an impact on their mental health and whether schoolteachers have an awareness of children's HL. Permanent HL is usually noted on school records and evident by children wearing hearing aids. However, with OM related HL this may not be noted and hearing aids may not be worn by all children. Therefore, as children's educational experiences have been found to be affected, further research exploring how educational experiences can be improved for children and the appropriate support that they require is needed to inform necessary suggestions for services to provide support for these children. Furthermore, as with the quantitative studies, studying the impact at more than one point in time would be invaluable.

2.7 Impact of OM related HL on cognitive development & education in children

As identified in the previous section, the impact that HL may have on psychosocial functioning in practice may lead to the educational experiences of children and adolescents also being affected. School is where children and adolescents spend most of their time in order to receive an education. Furthermore, the whole learning process at school is centred around interacting with others, whether this be with teachers or peers. As research has shown that OM related HL influences psychosocial behaviour, this impact whether through low self-esteem and low confidence in social interactions, anxiety or inattentive behaviour may have implications on academic performance/ability, which in the long run may implicate educational attainment, career paths and later mental health. This highlights the importance of exploring the educational experiences and outcomes of children with long-term OM related HL. Of course, a child's general cognitive ability will also influence academic outcomes, hence it is of importance to also consider the impact that long-term OM related HL may have on their cognitive development. This section explores how long-term OM related HL may impact cognition and academic ability and informs the research questions presented in Chapter 3.

2.7.1 OM related HL and cognition/education

Previous sections have discussed psychosocial development and how this may be impacted by long-term OM related HL. As psychosocial functioning is important for learning and cognition, a long-term OM related HL may also influence learning and cognition. The fluctuating, asymmetric hearing losses characteristic of OM related HL may make these processes more difficult for children to develop age appropriate language due to the inconsistency in auditory stimuli. Thus, as well as auditory processing, OM related HL may influence cognitive processes in relation to verbal ability.

Furthermore, the difficulties in discriminating speech sounds and analysing sound in difficult listening situations where there are competing sounds present may have implications for children in various areas, including the school classroom environment (Williams and Jacobs, 2009). These factors may then impede on their academic performance and learning as well as their cognition as the increased efforts and demands due to HL may impede cognitive function (Fulton et al., 2015). Cognitive ability in general is associated with educational attainment, occupation and health outcomes so deficiencies in cognitive ability may further influence academic performance and educational attainment (Plomin and von Stumm, 2018) Moreover, as discussed, the difficulties with social ability and psychosocial functioning that children with HL may experience and have been shown to display in qualitative studies, may impede on their learning. For children with long-term OM related HL, the implications may be long-term.

2.7.1.1 Overview of literature

Many studies have investigated the impact of OM & HL on cognitive and academic outcomes, with the concern of HL affecting language development and hence reading, writing and spelling ability (Williams and Jacobs, 2009; Gravel and Wallace, 1998). Yet, the evidence provided by these studies is inconclusive. Reviews of the literature have concluded that the heterogeneity in study design and methodology of studies has in part resulted in this inconsistency in findings as a majority of study designs have been retrospective cohort and case control studies. Furthermore, the definition and assessment of OM, let alone OM related HL has not been consistent across studies. Since then, the more recent studies have generally used a prospective design.

Most of the older studies conducted reported an association between OM in early life and cognitive and educational outcomes (Lindsay et al., 1999; Kaplan et al., 1973; Zinkus et al., 1978; Zinkus and Gottlieb, 1980; Pearce et al., 1988; Manders and Tyberghein, 1993; Brandes and Ehinger, 1981;

Howie et al., 1979; Hutton, 1983; Lewis, 1976; Updike and Thornburg, 1992; Webster et al., 1989). These outcomes included measures of IQ, language, reading and spelling ability. Nonetheless, many of these studies were conducted in retrospect with OM history obtained through parental report or medical records and thus their findings may have been subjected to bias. Furthermore, importantly, most studies did not account for HL, let alone other influencing variables. Therefore, whether differences between groups were due to OM related HL or other factors cannot be ascertained. Also, to take into consideration particularly with case control studies, is that case participants were selected from children who had already been referred to clinics for persistent OME or language and learning difficulties; hence, differences in outcome would most likely be reported.

While some prospective studies also reported associations with various outcomes e.g. reading, spelling and verbal abilities, these studies had not accounted for OM related HL and only measured presence of OM through pneumatic otoscopy, tympanometry or parental report and medical records (Schilder et al., 1993a; Peters et al., 1994; Teele et al., 1990; Paradise et al., 2000). Some prospective studies have reported little to no impact on cognition in early childhood in particular, with any negative associations reported being weak. This was particularly the case for a study conducted by Paradise & colleagues who studied middle ear effusion history in the first 3 years of life and its association with a range of outcomes (Paradise et al., 2000; Paradise et al., 2001b; Paradise et al., 2003a; Paradise et al., 2003b; Paradise et al., 2005; Paradise et al., 2007). They reported weak associations between middle ear effusion in the first year of life and measures of language and verbal cognition. Paradise et al. also conducted a series of studies based on a randomised controlled trial looking at the impact of early versus late insertion of ventilation tubes on development (Paradise et al., 2001b; Paradise et al., 2003a; Paradise et al., 2005; Paradise et al., 2007). The findings from these studies showed no association between timing of treatment and scores on outcomes at a range of ages (3-11 years), suggesting that longer lasting OM without intervention does not have adverse effects on development. These studies, however, were not conducted on a clinical sample and included children who presented with middle ear effusion when

assessed which may have been associated with AOM and of a short duration, so is likely to have not had any significant impact on outcomes. Furthermore, hearing levels were not assessed to indicate if the child had accompanying HL.

The issues with these studies discussed also apply to many other studies conducted in this area (Howie et al., 1979; Brooks, 1986; Lous et al., 1988; Lous, 1993; Bennett and Haggard, 1999; Luotonen et al., 1998; Hall et al., 2009; Fougner et al., 2017; Hall et al., 2017).

Prospective studies by Roberts et al. (1986; 1989; 1994; 1995a) also reported no significant association between OME and later cognitive outcomes including standardised measures of intelligence and academic achievement. These studies did not include assessment of hearing. In later studies however, where Roberts & colleagues assessed hearing levels as well as OME, associations were reported between HL between 6 months and 4 years and auditory discrimination and verbal maths skills at age 5 but not at later ages (6-8 years) (Roberts et al., 2000; Roberts et al., 2002). This is interesting as in their earlier studies where hearing level was not assessed, associations were not reported. Nonetheless, Roberts et al. reported that the child's home environment was more significantly correlated with academic skills than OME & HL were. Further limitations of Roberts' studies were their small sample sizes.

Larger longitudinal studies have since been carried out in which associations with OM and IQ and measures of academic ability have been reported (Silva et al., 1986; Teele et al., 1990; Bennett and Haggard, 1999; Johnson et al., 2000; Bennett et al., 2001; Hall et al., 2014; Hill et al., 2019). However, not all of these studies took account of hearing levels associated with OM. Of those that did, some studies used parent reports of HL or did not assess hearing at more than one time point. The impact of co-occurring mild visual and hearing difficulties arising from OM on educational achievement in the Avon Longitudinal Study of Parents and Children was studied by Hill et al. (2019). Hill et al. (2019) reported negative associations between both co-occurring and either visual or hearing difficulties at age 7 and achievement of level 4 or above in KS2 SATs and achievement of 5 or

more A*-C GCSE grades. Nonetheless, although this study used standardised measures of hearing, it only focused on difficulties at one time point from which inferences about long-term OM related HL cannot be made.

Furthermore, some studies reported stronger associations between socioeconomic and home factors and outcomes and some studies failed to account for these factors in their analyses. Methodological differences between studies makes it difficult to come to a conclusion on whether OM related HL influences cognition and academic ability. In order to draw conclusions specifically in relation to long-term OM related HL, findings from studies that have measured hearing levels using objective measures at more than one time point need to be reviewed.

2.7.2 Gaps in knowledge

There is wide inconsistency in the methodologies and findings of research examining the impact of OM related HL on cognition and academic ability. A key issue which has only been accounted for in a few studies is considering HL as part of the OM exposure and few account for the fluctuating nature of OM related HL by taking measures at more than one time point. There is also limited consideration of confounding factors.

There is therefore a need to focus on research where HL was measured using standardised measures and measured repeatedly over time, accounting for potential confounding factors e.g. socioeconomic and child and family factors. These issues can be addressed by focusing on longitudinal population studies. In addition, prospective studies designed to investigate the impact of long-term OM related HL in particular will ensure that informed conclusions can be made for the impact that this condition may have.

Qualitative studies exploring how OM related HL impacts the lives of children in a psychosocial context as discussed previously, have found that it impacts their educational experiences (Capewell, 2014; Tierney et al., 2015). These studies have first-hand delved into how the HL impacts children and have reported significant implications. It is important to explore this further and to investigate whether and how these poorer experiences influence academic ability and educational achievement outcomes.

2.8 Chapter summary

This chapter has served as an introduction to the work in this thesis which investigates the prevalence of long-term OM related HL and its impact on developmental outcomes. The literature lacks epidemiological evidence on OM related HL and presents inconsistent evidence of associations between OM and psychosocial development and cognition and academic ability, which may be due to methodological limitations as well as only a few studies accounting for HL. This also makes it unclear whether reported associations are due to OM related HL or other confounding factors. There is a need for largescale prospective longitudinal population studies to investigate the prevalence of both general OM related HL and long-term OM related HL. These studies need to ensure that they measure hearing levels along with OM and that these are measured at multiple points across time. Furthermore, these studies should also take measures of developmental outcomes to study associations between long-term OM related HL and development. Qualitative data has consistently shown how OM related HL impacts children's lives. Further qualitative research should be carried out to consolidate and build on these findings and to explore the support needs of these children.

Chapter 3. Research aims & plan

3.1 Introduction and rationale

As presented in Chapter 2, long-term OM related HL has the potential to influence children's development, particularly if the child is left without successful intervention and support. The literature on OM and its impact as outlined in Chapter 2 has informed us that there is very little research looking at OM & HL in the context where it could be classified as a long-term condition. This firstly brings to question whether long-term OM related HL is a significant condition that is prevalent amongst children. Secondly, the current literature on the general impact of OM on development provides inconclusive evidence as to whether OM itself has a significant impact on development. However, there are methodological limitations with most of this research - a key limitation being having not assessed and considered hearing levels.

Therefore, as there is an insufficient amount of evidence on long-term OM and HL, it stands that the next step would be to identify cases of long-term OM related HL, where HL is associated with OM and has validly and reliably been measured over time. This will then allow the investigation of whether the long-term HL experienced by these children has affected their development.

As detailed in the previous chapter, research on CHL has shown evidence of changes to the central auditory system occurring as a result of CHL, and findings from qualitative studies revealed that children with persistent OM related HL presented with implications to their emotional and social behaviours which in turn had a negative impact on their educational experiences (Tierney et al., 2015; Capewell, 2014). Studies on adults experiencing chronic middle ear problems and HL also

highlighted that even during adulthood, these individuals were having issues with their social skills as well as with education and at work (Skilton et al., 2016; Bidadi et al., 2008). These studies showed that the anxiety and negative self-image that individuals were experiencing in relation to their HL was impeding on their lives at school and work which may coincide with research which has shown that mental health problems in childhood influence academic performance (Agnafors et al., 2020).

As the current literature shows a possible association between long-term OM related HL and psychosocial/mental health and cognitive & educational outcomes across the life course, it is important to investigate these associations. A key reason for investigating this impact is to provide insight into how we can best support children presenting with long-term OM related HL and their families, as these children are a group whose difficulties caused by their HL may go unnoticed.

As there is little known about long-term OM related HL and how it may influence a child's development at present, services may not be supporting children who may present with a long-term OM related HL as they need. Much of this may be due to the lack of evidence for this condition and how it impacts children and their families. The guidance on OME suggests referral to ENT if the child presents with persistent HL which may be affecting their quality of life (NICE, 2016). Although the guidance acknowledges that persistent OM related HL may impede a child's quality of life, information regarding how to support these children and their families is lacking. For that reason, research which may guide the formation of such guidance is needed.

As there is some evidence in the current literature for long-term OM related HL having a potential negative influence on cognition and the psychosocial and educational experiences of children and adults, it is of importance that this is explored further to ensure that all children and their families who present with OM are given the relevant information to be informed about the potential impact that a long-term OM related HL may have, should this develop, especially as the HL may influence outcomes across the life course.

3.2 Research aim and questions

The overall aim of this research is to investigate the prevalence of long-term OM related HL in a prospective longitudinal population study and to explore the impact of this HL on developmental outcomes pertaining to psychosocial functioning, cognition and academic achievement.

The thesis will also detail qualitative research that has been designed to further explore any impact of long-term OM related HL as well as the information and support needs of families and children with long-term OM related HL.

The research will seek to answer three questions in particular:

1. What is the prevalence of long-term otitis media related hearing loss in children aged 7- 15 years?
2. Does long-term otitis media related hearing loss have a negative impact on children's development, specifically their psychosocial and cognitive and educational development?
3. What are the information and support needs of children and their families with long-term otitis media related hearing loss?

3.3 Research approach

The research presented in this thesis takes a mixed methods approach, utilising both quantitative and qualitative methods.

Estimating the prevalence of long-term OM related HL will require quantitative methods. Quantitative methods can also be used to test for associations between long-term OM related HL

and developmental outcomes. However, to further explore the information and support needs of families and children, qualitative methods are best suited. More detailed data obtained from those affected may offer us insights into how the condition impacts them. Furthermore, using qualitative methods will allow exploration of any influence of long-term OM and HL on child development rather than solely identifying an association, as well as obtaining detailed data on their support needs. This would help to tailor the information and support to be provided, best to suit the needs of these children and their families. Involving those affected with the condition as well as individuals who play a significant role in these children's lives will provide rich data from those affected that will help to guide patient centred care.

Using a mixed methods approach, therefore is best suited to answer these research questions to sufficiently meet the needs of children with long-term OM related HL. The combination of both quantitative and qualitative methods will answer the research questions more fully than quantitative or qualitative methods alone would (Creswell and Plano Clark, 2011; Scammon et al., 2013). Although this thesis only presents the findings of the quantitative strand, had the qualitative research been carried out, a convergent approach would have been taken and findings were to be integrated from both strands after each dataset had been analysed accordingly with the appropriate quantitative and qualitative methods of data analysis (Creswell and Plano Clark, 2018).

3.4 Research design

3.4.1 Systematic review

As potential specific implications to children's educational experiences have been indicated, this thesis will begin with a systematic review of studies in the current literature which have been

conducted on children with long-term OM related HL and have assessed its potential impact on educational/cognitive outcomes. The literature addressed in Chapter 2 involved studies looking at OM in general. Therefore, a more focused and structured review identifying papers looking at OME and HL that can be classed as long-term OM related HL is required to identify, appraise and collate all available relevant empirical evidence in this area and to further consolidate gaps in this area of research (O'Hagan et al., 2018; Petticrew, 2001). The initial search revealed that many studies have been conducted looking at the impact of OM on cognition and education, whereas only few studies have focused on psychosocial development. Furthermore, prospective longitudinal studies focusing on psychosocial outcomes are lacking. Hence, the systematic review will focus on prospective studies on long-term OM related HL and its impact on cognitive and educational outcomes. Findings from this review were used to inform the next stage of research conducted as part of this thesis.

3.4.2 Investigating the prevalence of long-term OM related HL and its impact on developmental outcomes in a prospective longitudinal population cohort study

As this thesis is looking at long-term OM related HL, population data on prevalence obtained across a range of time points is needed. Persistent OM that has been covered to date usually refers to OME lasting 3 months. Studies which have looked at OME lasting more than 3 months, have generally looked at OME in early childhood with only a few looking at later ages in childhood. Furthermore, the OM during early childhood has generally been the focus on OM related research. OM can occur across a range of ages, hence OM and hearing data across a range of ages in childhood is needed.

Longitudinal prospective population-based cohort studies are required to provide a general estimate for the prevalence of long-term OM related HL. This study design provides large numbers of participants to follow over time which means it is well suited to study a long-term condition and its impact overtime (Sedgwick, 2013). Measurements of exposures (OM and HL) can be made before

any influence has been made on children's development while also allowing to study and control for interactions with other relevant variables in the analyses and avoiding recall bias (Sedgwick, 2013).

Data from the Avon Longitudinal Study of Parents and Children (ALSPAC) will be analysed to estimate the prevalence of long-term OM related HL between the ages of 7 & 15 years in this cohort and its impact on developmental outcomes between the ages of 10 & 15-16 years. ALSPAC is the only longitudinal study in the UK to have objectively collected repeated measures of OM and hearing during mid-childhood on a large cohort of children. The measures of hearing at these later ages in childhood mean that analysing the ALSPAC data to investigate long-term OM related HL is ideal. Analysis of the ALSPAC data will add invaluable evidence to the research on OM related HL.

3.4.3 A plan to qualitatively explore the impact of long-term OM related HL on children and their support needs

This thesis will also present a detailed plan for a qualitative study to further explore the impact of long-term OM related HL on psychosocial functioning and educational experiences.

Chapter 4. A systematic review of the impact of long-term OME related HL on children's cognitive development and academic ability

4.1 Introduction

This chapter describes a systematic review undertaken on the literature surrounding long-term OME related HL and its impact on cognitive and educational outcomes.

Reviews of studies looking at the impact of OME on speech and language as well as cognition and academic skills have been carried out previously (Williams and Jacobs, 2009; Roberts et al., 2004a; Roberts et al., 2004b; Jung et al., 2005; Gravel and Wallace, 1998; Lous, 1995). These reviews report that there is insufficient evidence that OME has any impact; however, most of the studies reviewed while differing in design, have focused on short-term cases of OME and have not accounted for HL in all cases. This is a limitation as it is the associated HL that is thought to influence development (as reviewed in Chapter 2). The aim of this thesis is to investigate the impact of long-term OM related HL as opposed to that of a shorter nature; hence there is a need to first conduct a systematic review of previous research in which OME related HL is the exposure, not OME. Furthermore, there is a need to focus on prospective studies which measure OME and HL longitudinally in order to identify long-term OME related HL and not transient OME. Finally, there is a need to focus on OME and HL as opposed to AOM or OM or MEE in general, to identify the effect of long-term OM related HL rather than episodes of AOM.

4.2 Methods

The Systematic Reviews to Answer Health Care Questions Guide (Nelson, 2015) and Cochrane Handbook for Systematic Reviews of Interventions chapter on Synthesizing and presenting findings using other methods (McKenzie and Brennan, 2020) were followed to complete this systematic review. A question was first formulated in order to base the literature search on. Searches were then carried out in seven online databases. These processes are outlined below.

4.2.1 Question formulation

As the area of cognitive development is broad with there being many cognitive processes, intelligence quotient (IQ) was selected to be studied as a general measure of cognition. While intelligence refers to adaptive behaviour it is also generally defined as 'a very general mental capability that, among other things, involves the ability to reason, plan, solve problems, think abstractly, comprehend complex ideas, learn quickly and learn from experience' (Gottfredson, 1997), thus is a general measure of cognitive ability. Intelligence can be reliably measured by standardised tests. These tests are amid the most accurate psychological tests and assessments and are scored to give an intelligence quotient (IQ) (Gottfredson, 1997). The IQ score is a quantification of an individual's intelligence relative to age and is strongly related to life outcomes such as educational, occupational, economic and social outcomes (Matzel and Sauce, 2017; Gottfredson, 1997). Furthermore, intelligence tests are split into sections which test verbal and non-verbal intelligence separately. As HL may influence speech and language outcomes, verbal cognitive ability may be more greatly influenced, and IQ test scores can demonstrate the effect on this individual component of IQ as well as overall IQ. Using a standardised measure ensured validity in measuring outcomes and allowed comparison between studies. Moreover, shorter, less time-consuming

measures such as IQ are often used by large epidemiological studies as opposed to more in-depth measures of cognition.

Studies which focused on outcomes measuring academic ability were also reviewed. These included measures of academic skills (e.g. reading ability, writing and mathematical ability) and performance/achievement such as grades/scores on standardised school tests or tests of academic skills.

The research question was developed using the PICO format (Sackett et al., 2001), where the Intervention was the exposure:

P Children

I Long-term OME and hearing loss

C Normal hearing

O IQ score/ academic ability test grades or scores

➔ **Do children with hearing loss associated with long-term otitis media with effusion have a lower IQ or poorer academic ability than children without hearing loss?**

As treatment is provided in randomised controlled trials (RCT), this changed the PICO format whereby the intervention and comparison groups were early surgery for ventilation tubes and watchful waiting/late surgery as shown below; however, the question remained the same.

P Children

I Early surgery

C Watchful waiting/late surgery

O IQ score/ academic ability test grades or scores

4.2.2 Literature search

A systematic search was performed to look for:

a) Prospective cohort studies;

- To ensure that the measures of exposure (OME & HL) were taken prior to any outcomes. This would ensure that measures of OME & HL were taken at baseline and children were followed up over time to obtain measures relating to IQ and academic ability. This would also avoid recall bias.
- To enable identification of long-term OME related HL as opposed to experience of OME and HL at one time point, as measures of OME and HL would be taken at more than one occasion over time.
- This study design was suited to study and control for interactions with other relevant variables in the analyses.
- As they are also more likely to include large numbers of participants to follow over time, meaning they were well suited to study a long-term condition and its impact over time (Sedgwick, 2013).

b) Randomised Controlled Trials (RCT);

- Which compared outcomes between groups of children with persistent OME and HL lasting more than three months, who were randomly allocated to an early treatment or no/late treatment group. In these RCTs, outcomes would have been

compared between groups before and after treatment. If differences in outcome between the two treatment groups were found, this would suggest that these were due to the duration of OME and HL experience.

The search focused on these two study designs as they are reported to be the highest in quality (Bhopal, 2016).

4.2.3 Data sources

Searches for relevant studies were carried out by Aleema Rahman (AR) in the following databases:

- Web of Science
- PubMed
- Scopus
- PsycArticles (via ProQuest)
- CINAHL (via EBSCO)
- Embase (via OVID SP)
- Cochrane Library

The list of databases and terms searched are presented in Table 4.1. Boolean operators were used, and MeSH terms were used with databases that had the facility to use MeSH search terms.

Table 4.1 List of databases searched for relevant papers for systematic review, along with the search terms used and the number of hits received for each database

Database	Time covered	Search terms	Number of papers
Web of Science	1970-2020	((“otitis media” OR "otitis media with effusion" OR OM OR OME OR "glue ear" OR "chronic OME" OR "persistent OME" OR "long-term OME" OR "middle ear effusion" OR “conductive hearing loss”) AND (children OR paediatrics OR pediatrics OR "school children" OR infants OR toddlers OR teenagers OR adolescents OR "young people") AND ("cognitive development" OR cognition OR "academic achievement" OR	485

		education OR IQ OR intelligence OR "educational attainment" OR "educational outcomes" OR "educational achievement" OR "educational status" OR "academic success" OR “academic performance” OR "school attainment" OR "assessment outcomes" OR "education of the hearing impaired" OR "intelligence tests" OR “intelligence quotient” OR "cognition disorders"))	
PubMed	1980-2020	((((((("School children" OR "young people" OR toddlers OR (("Child"[Mesh]) OR "Pediatrics"[Mesh]) OR "Adolescent"[Mesh]))))) AND ((((("chronic otitis media with effusion" OR "persistent otitis media with effusion" OR "long-term otitis media with effusion"))) OR ((("Otitis Media with Effusion"[Mesh]) OR "Otitis Media"[Mesh]) OR "Hearing Loss, Conductive"[Mesh]))) AND (((((("Educational Status"[Mesh]) OR "cognitive development" OR ("Cognition"[Mesh] OR "Cognition Disorders"[Mesh] OR "academic achievement" OR "Academic Success"[Mesh]) OR "Academic Performance"[Mesh]) OR ("Education"[Mesh] OR "Education of Hearing Disabled"[Mesh])) OR "educational attainment" OR "educational outcomes" OR "educational achievement" OR "school attainment" OR ("Intelligence"[Mesh] OR "Intelligence Tests"[Mesh] OR "Wechsler Scales"[Mesh] OR "cognitive development" OR IQ OR "Intelligence Quotient")))	338
Scopus	1972-2020	(("otitis media with effusion" OR ome OR "glue ear" OR "chronic OME" OR "persistent OME" OR "long-term OME" OR "middle ear effusion" OR "conductive hearing loss"))) AND (TITLE-ABS-KEY ((children OR paediatrics OR pediatrics OR "school children" OR infants OR toddlers OR teenagers OR adolescents OR "young people"))) AND (TITLE-ABS-KEY (("cognitive development" OR cognition OR "academic achievement" OR education OR iq OR intelligence OR "educational attainment" OR "educational outcomes" OR "educational achievement" OR "educational status" OR "academic success"))	339
PsycInfo	1985-2020	("otitis media with effusion" OR ome OR "glue ear" OR "chronic OME" OR "persistent OME" OR "long-term OME" OR "middle ear effusion" OR "conductive hearing loss") AND (children OR paediatrics OR pediatrics OR "school children" OR infants OR toddlers OR teenagers OR adolescents OR "young people") AND ("cognitive development" OR cognition OR "academic achievement" OR education OR iq OR intelligence OR "educational attainment" OR "educational outcomes" OR "educational achievement" OR "educational status" OR "academic success")	50
CINAHL	1970-2020	((MH "Otitis Media") OR (MH "Otitis Media with Effusion") OR (MH "Middle Ear Ventilation") OR (MH "Ear, Middle") OR "otitis media with effusion OR OME OR glue ear OR chronic	30

		ome OR persistent ome OR long-term OME OR middle ear effusion") AND ((MH "Child") OR (MH "Child Day Care") OR (MH "Adolescence") OR (MH "Child Development: Adolescence (12-17 Years) (Iowa NOC)") OR "children OR adolescents OR youth OR child OR teenager" OR (MH "Pediatrics") OR (MH "Schools") OR (MH "Schools, Secondary") OR (MH "High School Graduates") OR (MH "Students, High School") OR (MH "Schools, Middle")) AND ((MH "Academic Performance") OR (MH "Academic Achievement") OR (MH "Academic Failure") OR (MH "Achievement Tests") OR (MH "Educational Measurement") OR (MH "Outcomes of Education") OR (MH "Education") OR (MH "Education, Non-Traditional") OR (MH "Cognition") OR (MH "Cognition Disorders") OR (MH "Mild Cognitive Impairment") OR (MH "Intelligence") OR (MH "Intelligence Tests"))	
Embase	1970-2020	("otitis media with effusion" OR OME OR "glue ear" OR "chronic otitis media with effusion" OR "persistent otitis media with effusion" OR "long-term otitis media with effusion" OR "middle ear effusion" OR "otitis media" OR "conductive hearing loss") AND (children OR paediatrics OR pediatrics OR "school children" OR infants OR toddlers OR teenagers OR adolescents OR "young people" OR child) AND ("cognitive development" OR cognition OR "academic achievement" OR education OR IQ OR intelligence OR "educational attainment" OR "educational outcomes" OR "educational achievement" OR "school attainment" OR "assessment outcomes" OR " intelligence tests" OR "cognition disorder" OR "educational status" OR "academic success" OR "education of hearing impaired")	936
Cochrane Library	1970-2020	Cochrane MeSh terms: Otitis media OR Otitis media with effusion AND Child AND Cognition OR Intelligence OR Educational status OR Academic success	5

The titles and abstracts of all search results were screened independently by Aleema Rahman (AR) and Amanda Hall (AH) to identify potential papers for review after which the full text of potential papers was reviewed to determine eligibility. The reference lists of selected papers were then searched for any other eligible studies that were not picked up through the database searches. Differences of opinion were resolved through discussion and review of the selection criteria. Final searches were carried out in January 2021.

4.2.4 Selection criteria

Papers selected included those which:

- Had a prospective cohort study or RCT design
- Focused on children from any population presenting with OME and HL lasting >3 months at any age in childhood
- Had baseline prospective measures of OME and HL that were not self-report and followed up children overtime
- Measured HL as part of exposure and not an outcome
- Had a prospective measure of IQ/academic ability at follow up from baseline

Papers were excluded if:

- Participants had sensorineural hearing loss (SNHL)
- There was no measure of hearing threshold at baseline and during the duration of OME experience studied
- OME/HL was measured through self/parental report measures and not standardised measures to avoid inaccurate measurement
- They were review papers
- They were not written in English

4.2.5 Data abstraction

A data abstraction form was created using an Excel spreadsheet to abstract key data and information about the selected studies. The authors, title and year of the paper were noted as well as the country that the study took place in and study details including the aim of the study, study design, study

population, sample size and characteristics, exposure and outcome measures (and the ages these were measured), confounding factors considered in analyses, the statistical test used and key findings of the study. The data abstraction form can be found in Appendix A.

4.2.6 Quality assessment

The Critical Appraisal Skills Programme (CASP) checklist for cohort studies was used to critically appraise the studies (CASP, 2018). The PRISMA checklist for systematic reviews and meta-analyses was also referred to (Moher et al., 2009). Furthermore, the Tool to Assess Risk of Bias in Cohort Studies (McMaster University, 2017) was used to assess the risk of bias of each cohort study that was reviewed.

4.2.7 Evidence synthesis

The initial plan was to conduct an aggregative synthesis of the studies using a meta-analysis. However, the studies selected for review differed not only by the outcome variables studied and by the outcome measures used, but also by the age of children studied and how the exposure was characterised. It was anticipated that a meta-analysis could be carried out for studies which used the same approach and outcome measure e.g. IQ and other standardised measures, however, studies that used a similar approach failed to report the statistics needed to convert effect sizes into one measure for comparison, hence, a quantitative approach through meta-analysis was not taken due to the difficulty of pooling data from heterogeneous studies. Hence, a narrative synthesis of the studies was carried out.

4.3 Results

The number of hits obtained from each database is presented in Table 4.1. Combined, this gave a total of 2,183 papers. After removing duplicate papers, this gave a total of 1,488 papers. Six relevant papers were selected for review. Two of these six papers were based on one study which reported outcomes at different ages in separate papers. These two papers were considered as one study (Roberts et al., 2000; Roberts et al., 2002). Thus, five studies were selected for review. These were all prospective cohort studies. No RCTs were eligible for review.

A flowchart demonstrating the selection process of papers selected for review is presented in Figure 4.1.

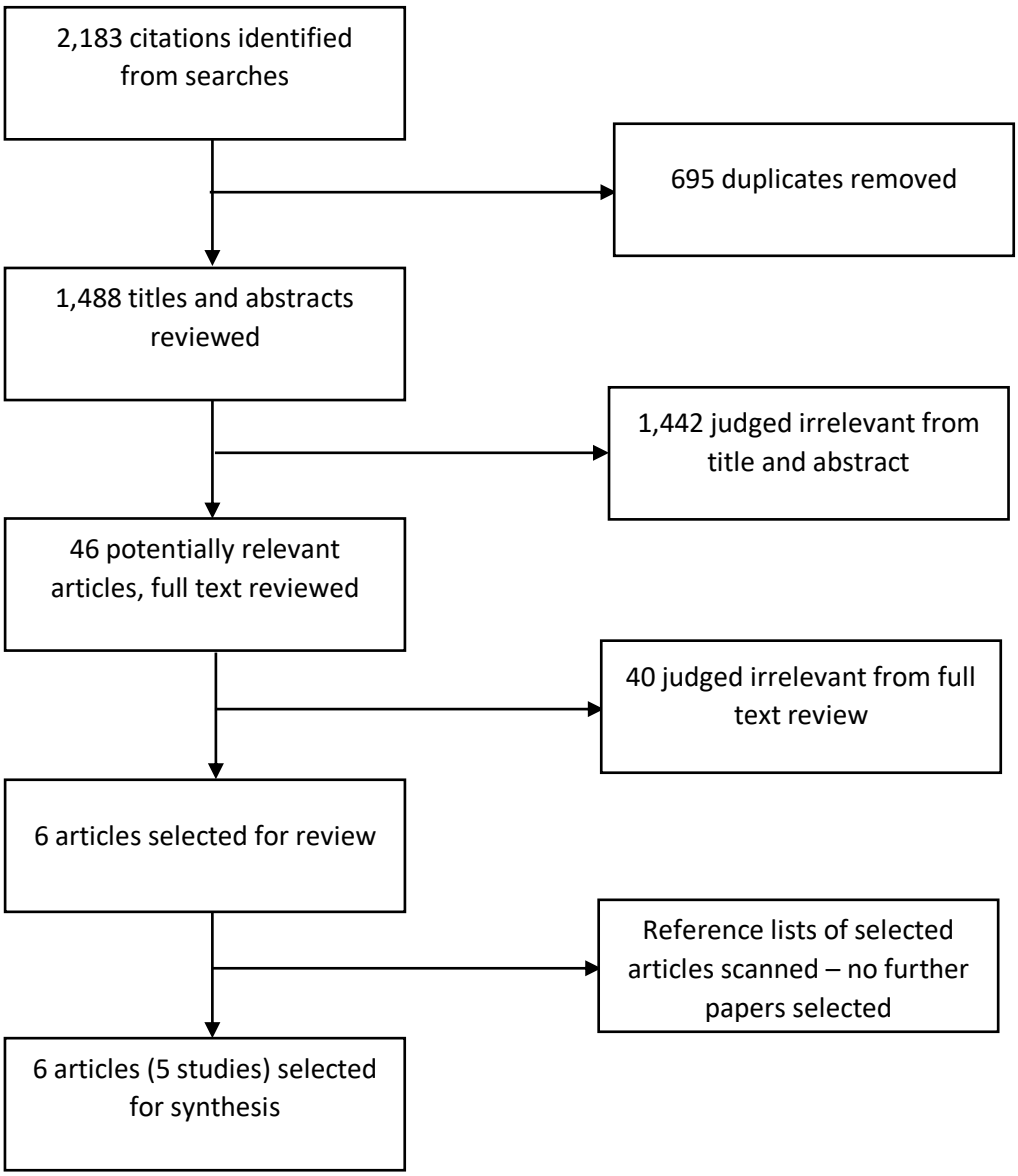


Figure 4.1 Selection process of studies for the systematic review of studies investigating the impact of long-term OME related HL on cognition/academic ability

Many prospective studies have been conducted on the impact of OME on child development. However, only a few met the inclusion criteria for this systematic review as the aim was to review high quality studies which focused on the HL associated with OME and that of a longer nature. This meant that many well-known studies in this area were excluded due to failure to assess hearing levels validly and studying middle ear effusion in general and OM of a shorter nature. Table 4.2 summarises the reasons for their exclusion.

Descriptive information for the five selected prospective studies is presented in Table 4.3.

Table 4.2 Prospective studies focusing on the impact of OM on cognitive development and academic ability that were excluded from systematic review and reasons for exclusion

Authors	**Reason for exclusion**
Paradise et al. (2000); Paradise et al. (2001a); Paradise et al. (2003a); Paradise et al. (2003b); Paradise et al. (2005); Paradise et al. (2007)	The study sample consisted of children with middle ear effusion in general so those with OME could not be distinguished from those with AOM, and tested hearing levels only when effusion was present
Johnson et al. (2000)	The study looked at middle ear effusion status – middle ear effusion was diagnosed if effusion was present with a type B tympanogram. Hearing acuity was only assessed to ensure that the child had normal hearing at the time of cognitive testing and to exclude children with sensorineural hearing loss, not as a measure of exposure
Howie et al. (1979)	No measure of HL
Brooks (1986)	No consistent measure of HL as exposure – audiometry carried out only at age 15/16 years follow up
Roberts et al. (1986); Roberts et al. (1989); Roberts et al. (1994); Roberts et al. (1995a)	No measure of HL
Roberts et al. (1995b); Roberts et al. (1998)	Cognitive ability measure was not a measure of IQ
Lous et al. (1988)	OM histories and suspected HL obtained from parents and case records
Knishkowy et al. (1991)	HL not measured as part of the exposure but as an outcome
Schilder et al. (1993b)	Did not measure hearing levels at time of OME diagnosis so was not studying OME related HL
Teele et al. (1990)	The study looked at middle ear disease including both AOM and OME and did not measure hearing levels
Peters et al. (1994)	Did not measure hearing level when OME was present
Gravel et al. (1995)	OM was not limited to OME and was diagnosed using pneumatic otoscopy. Hearing levels were assessed after diagnosis to compare between groups, not as the exposure.
Bennett and Haggard (1999)	OME and HL were measured by parental report
Silva et al. (1986)	OME was defined through tympanometry and otoscopy at age 5. HL was assessed as an outcome, not as the exposure.
Luotonen et al. (1998)	OME history obtained through parental report
Hall et al. (2009)	Children were already identified as having learning difficulties at start of study
Hall et al. (2017)	Hearing was assessed at one point only – there were no measures over time thus long-term OME related HL could not be determined
Fougner et al. (2017)	Parent reported OM episodes, no measure of hearing

Table 4.3 Descriptive information for the six studies selected for review

Authors	Year published	Population/ sample characteristics	*n*	Age of participants when recruited	Measure of OME/hearing	Age OME/hearing measured	How long-term OME related HL was determined	Outcome measure	Age outcome measured	Confounders considered	Method of analysis
Lous	1993	Unselected cohort of children attending one of 13 schools across two Danish municipalities	366	7 years	Pneumatic otoscopy Tympanometry Pure tone screening	7-8 years	Mean hearing threshold of the 5 hearing screening measures taken across the year	Academic ability: OS-400 Silent Word Reading test	8 years	N/A	Regression
Bennett et al.	2001	Dunedin Cohort – a longitudinal birth cohort study. Births between 1 April 1972 and 31 March 1973 in Dunedin City, New Zealand	962	Recruited at birth	Tympanometry Otomicroscopy. Audiometry	5, 7 & 9 years	Cumulative history of OME measured between ages 5-9 years. Hearing thresholds were also obtained when measuring OME at each age.	IQ: Verbal, non-verbal and total IQ assessed using WISC[1] at 11 & 13 years Academic ability: Dunedin spelling tests at 11 & 13 years Burt reading test at 11,	11-18 years	Sex SES	Regression

[1] Wechsler Intelligence Scale for Children- Revised, (Wechsler, 1974)

								13, 15, & 18 years			
Augustsson & Engstand	2001	A birth cohort of Swedish children from Örebro, born in 1980 and living in the area between 1984 -1995.	2095	Recruited at birth	Oto-microscopy, tympanometry and audiometry (from medical and ENT records)	From 4 years up to 14 years	Children referred to ENT clinics after having SOM[2] which has not resolved within 3 months. Medical records checked for treatment with VTs[3] during every 2-year period.	Academic ability: Grade at the end of 9th grade	15/16 years (9th grade)	Sex General health (days spent in hospital)	Regression

[2] Secretory otitis media – another term for OME
[3] Ventilation tubes (grommets)

Roberts et al.	2000	Black children primarily from low income families recruited from 9 country based childcare programmes	85	6 to 12 months	Pneumatic otoscopy, tympanometry Visual Reinforcement Audiometry (VRA) between 6 months & 2.5 years Play audiometry between 2.5 & 4 years to test hearing acuity.	From 6 months up to 4 years	Children's ears examined weekly/biweekly up to 5 years (hearing assessed up to 4 years) – percentage of time with OME & with HL computed. Hearing tested at entry and every 3 months after; and during weeks 1, 4, 7 and 13 after OME diagnosis and when there was a change in OME status.	Academic ability: 3 subtests from the WJPB[4]: Letter word identification, Applied problems & Incomplete words	5 years	Gender Whether family lives in poverty Maternal education Quality of home environment Quality of childcare environment	Regression

[4] Woodcock-Johnson Psychoeducational Battery (Woodcock & Johnson, 1990)

Roberts et al. (same study as above)	2002	Black children primarily from low income families recruited from 9 country based childcare programmes	83	6 to 12 months	Pneumatic otoscopy, tympanometry Visual Reinforcement Audiometry (VRA) between 6 months & 2.5 years Play audiometry between 2.5 & 4 years to test hearing acuity.	From 6 months up to 4 years	Children's ears examined weekly/biweekly up to 4 years – percentage of time with OME & with HL computed. Hearing tested at entry and every 3 months after; and during weeks 1, 4, 7 and 13 after OME diagnosis and when there was a change in OME status.	Academic ability: 3 subtests from the WJPB[4]: Letter word identification, Applied problems & Incomplete words	Between 4 years & second grade (8 years)	Gender Home environment Maternal education	Pearson Correlations Generalised linear mixed models

Hall et al.	2014	10% random sample of children from ALSPAC, a longitudinal birth cohort study on children born in Avon in Bristol, UK between 1 April 1991 and 31 December 1992	1155	Recruited at birth	Tympanometry to detect OME. McCormick Toy Test to test hearing acuity	Up to 5 years	Cumulative OME and hearing loss scores over first 5 years	IQ: Verbal and non-verbal IQ assessed using WPPSI[5] at 4 years WISC-III[6] at 8 years	4 and 8 years	Sex Birthweight Gestational age Maternal education level Housing tenure Parental social class Maternal age Parity Maternal smoking during pregnancy	Regression

[5] Wechsler Pre-school & Primary Scale of Intelligence (Weschler, 1990)
[6] Wechsler Intelligence Scale for Children, (Wechsler, 1992)

4.3.1 Quality assessment

All studies selected for review had repeated measures of hearing. IQ was studied as an outcome by two of the selected prospective studies (Bennett et al., 2001; Hall et al., 2014) with one of them also studying measures of academic ability. The remaining prospective studies (Lous, 1993; Roberts et al., 2000; Roberts et al., 2002; Augustsson and Engstand, 2001) looked at the association of long-term OME & HL with measures of academic ability. The method of analysis and detail of reported statistics varied between studies and hence the effect sizes from each study could not be pooled. Results of each individual study are presented later, following the review of quality of each study. For a summary of the critical appraisal of each study, the reader should refer to Table 4.4.

4.3.1.1 Appropriateness of study design

Studies selected for this review were based on their study design – all studies had to be prospective cohort studies or RCTs. No suitable RCTs were selected for review. The five prospective studies were longitudinal cohort studies - the most suitable design in order to determine whether the OME and HL experienced was long-term, to study any long-term effects, and to ensure that the exposure preceded any effects on the outcome of interest. More so, the sample from two of the studies were selected from longitudinal birth population studies, thereby allowing for control of cohort effects as each child was born within a specified time period (Caruana et al., 2015). Furthermore, population studies allow follow up of large numbers of people within a defined population, providing important epidemiological information (Szklo, 1998). However while data on various factors were collected from birth, OME & hearing data were not obtained from birth in these two studies (Bennett et al., 2001; Hall et al., 2014). Although they initially screened for OME and HL from age of 4, one study did

obtain ENT data from birth (Augustsson and Engstand, 2001). All studies assessed for OME and HL at regular intervals across time, which allowed for identification of OME and HL of a longer nature.

4.3.1.2 Choice of outcome measure

One out of the five studies looked at the impact of OME and HL on IQ only, three used measures of academic ability only and one study used measures of both IQ and academic ability. The measure of IQ was consistent across studies with the Wechsler Intelligence Scales for Children (WISC) being used, which are validated measures of intelligence (Matzel and Sauce, 2017). Measures of academic ability consisted of subtests from validated measures such as the Woodcock-Johnson Psychoeducational test battery., the Burt reading test, the OS 400 Silent Word reading test and standardised attainment grades - measures of academic achievement rolled out by the government, so were measures that are used nationally. While most measures used were standardised measures, not all measures were. The spelling measure used by Bennett et al. (2001) was developed by the Dunedin study team. Furthermore, the standardised grades used by Augustsson and Engstand (2001) were partly based on teacher report on behaviour and attitude at school. While, behaviour may influence educational outcomes, this remains a subjective measure. Nonetheless, in Sweden, these grades obtained at ninth grade provide the first general assessment of the academic achievements of children, nationally.

Table 4.4 Summary of critical appraisal of the five studies selected for review

Authors	Strengths	Weaknesses
Lous (1993)	Exposed and non-exposed groups drawn from same population Children recruited from across two Danish areas Reported who was not part of the sample at follow up for outcome assessment	Did not run analysis adjusting for potential confounding No report of sample demographics Data on hearing thresholds not given Did not report on precision of results Hearing not measured at each interval
Augustsson and Engstand (2001)	Large sample Controlled for sex and general health Avoided detection bias through use of linked data Exposure measured over greater age range than other studies (4-14 years) Exposed and non-exposed groups drawn from same population	Limited control for confounding No report of sample demographics No inclusion/exclusion criteria Data on hearing thresholds not given Grades used as outcome measure was made up in part by teacher report No detail on missing data Did not report on precision of results
Bennett et al. (2001)	Large sample taken from a longitudinal birth population study Controlled for sex and SES Studied outcomes at a greater and later age range: 5, 7, 9, 11, 13, 15 & 18 years Exposed and non-exposed groups drawn from same population Studied a range of outcomes	Attrition (details of loss to follow up not given) Did not account for range of confounding factors No details of illnesses/disabilities No inclusion/exclusion criteria Sample more socially advantaged than rest of country Data on hearing thresholds not given Did not report on precision of results
Roberts et al. (2000); Roberts et al. (2002)	Children recruited from different settings Examined more frequently for OME & HL than in other studies – weekly/biweekly Assessed by 2 trained nurses using pneumatic otoscopy with a very high inter-observer agreement with an otolaryngologist so investigator error and bias reduced Audiologists were blinded to child's ear status and when assessing cognitive outcomes, assessors were blind to ear status and hearing levels.	Small sample Study limited to only African American children from low income families studied No inclusion/exclusion criteria

	Same outcome measures used at different ages Exposed and non-exposed groups drawn from same population Studied a group of children not typically studied	
Hall et al (2014)	Exclusion criteria given Large sample from a longitudinal birth population study Random 10% sample from ALSPAC – avoids selection bias Controlled for the most confounders Fairly large sample Investigator bias was avoided as IQ tests were carried out by trained psychologists who were blinded to the grouping of the children Exposed and non-exposed groups drawn from same population Attrition rates could be calculated from information provided	Hearing not measured at each interval Opportunistic sampling originally for ALSPAC – reduces generalisability of sample ALSPAC cohort – advantaged sample No details of illnesses/disabilities

4.3.1.3 Measure of hearing

As HL was the key exposure of interest for this review, it is crucial that validated tests of hearing were used by the studies selected for review. Hearing was assessed using audiometry, the standard test of hearing, in Bennett et al. (2001), Roberts et al. (2000); Roberts et al. (2002), Augustsson and Engstand (2001) and Lous (1993). The McCormick Toy Test (MTT) was used in Hall et al. (2014). The MTT is a word recognition threshold test that tests ability to hear speech. Although it is not a direct measure of hearing, it is strongly related to hearing ability so does not specifically lack validity in measuring hearing level (Summerfield et al., 1994). Having said this, hearing was assessed less frequently than OME measures were taken but was still assessed over time. This was also the case in the study by Lous (1993) where hearing was assessed on 5 occasions, whereas tympanometry was carried out on 10 occasions. This may mean that the occurrence of long-term OME related HL was underestimated in this study.

4.3.1.4 Sample characteristics

When judging the external validity of a study, the sample size and characteristics need to be examined in order to determine the generalisability of the findings to other populations outside of the sample. The prospective longitudinal population studies had the advantage of having large sample sizes and so greater precision and power to detect differences between the exposed and unexposed (Bennett et al., 2001; Hall et al., 2014; Augustsson and Engstand, 2001). These sample sizes ranged from 2095 to 366. Nevertheless, the two birth cohort studies generally recruited participants from more socially advantaged backgrounds. Augustsson and Engstand (2001) also reported a compressed range of social class in Scandinavian countries. As socioeconomic background has been shown to be associated with both OM and education (Casselbrant and Mandel, 2003 ; Baraibar, 1997; Caceres Udina Ma et al.,

2004; Abou-Halawa and Alhumaid, 2014; Nieman et al., 2016; Adeyemo, 2012; Almudhaibery et al., 2019; Banerjee, 2016; Memon et al., 2016; UK Government, 2016), findings from these studies may not be representative to children from backgrounds which differ to those studied.

In comparison to these large population studies, the sample in Roberts et al.'s study was small and thus, makes it more difficult to ascertain whether there is a real effect or whether this is due to random variation. Furthermore, it can be criticised as not being a representative sample of the US general population as only African American children were studied. However, many studies conducted in this area have only recruited children from a Caucasian background so the study can be credited for providing data on African American children who are generally not studied. In addition, 74.7% of the children were from families with low income so again this gives valuable data on a sample that differs from those in other studies, which looked at more socially advantaged children and families. The children were recruited from nine centre based childcare programmes so not from one setting which adds to the generalisability of the sample of a group of children who are not usually studied. Lous (1993) did not report on the characteristics of the sample studied, thereby it cannot be inferred whether findings are representative of the general population.

4.3.1.5 Risk of bias

This section reports specifically on the risk of bias present in each study. The Tool for Assessing Risk of Bias in Cohort Studies was used to assess each study in terms of whether they presented with a low or high risk of bias. The tool consists of seven questions based on the domains of bias discussed above in order to determine the level of bias present in each domain. There were four answers to choose from followed by justification. These were: 1) 'definitely yes' 2) 'probably yes' 3) 'probably no' 4) 'definitely no'. Generally, questions answered 'definitely yes' represented a low risk of bias and questions answered 'definitely no' represented a high risk of bias. 'Probably yes' still indicated a

potentially low risk of bias and 'probably no' indicated a potentially high risk of bias. The risk of bias tables are presented in Appendix B. Table 4.5 displays the summary of risk of bias ratings for all studies. Green indicates a low risk of bias and red indicates a high risk of bias. Yellow indicates a medium risk of bias ('probably yes' answers). Each domain of bias is discussed below.

4.3.1.5.1 Selection bias

The procedures used to select subjects for participation in the studies can result in selection bias, whereby subjects are selected based on certain characteristics that may influence study participation (Rothman et al., 2008). This is a problem as the relation between exposure and outcome may differ for those who participate and those who do not. Although large birth cohort studies, reduce the likelihood of certain subjects being selected for participation, selection bias was present with the two birth cohort studies by Hall et al. (2014) and Bennett et al. (2001). While a random 10% of the ALSPAC cohort was studied in Hall et al. (2014), which reduces selection bias, participants of the ALSPAC study were mainly of white and higher socioeconomic background. Thus, findings from this study would not be representative of those who are non-white and of lower socioeconomic backgrounds. This is also the case for participants for the study by Bennett et al. (2001) which also included participants of a higher socioeconomic background.

The study by Roberts et al. was designed to study a sample of African American children who are typically not included in studies. Nonetheless, selection of participants was based on day care attendance. Although, a majority of the children in the sample were reported to belong to lower socioeconomic backgrounds, selection may be biased in the way that children from families who could not afford day care were not included. Furthermore, day care attendance has been found to be associated with a higher risk of developing OM.

Both the studies by Augustsson and Engstand (2001) and Lous (1993) involved national cohorts and the authors did not report on specific participation selection procedures. Nonetheless, all studies recruited children with and without OME and HL from the same cohort, which ensures that selection bias was not present between the exposure and non-exposure groups.

4.3.1.5.2 Attrition bias

Although longitudinal studies allow us to study long-term conditions and long-term effects, a limitation present with these studies is attrition bias from loss to follow up (Twisk and de Vente, 2002). Selection bias may also be present through attrition bias in longitudinal studies whereby participation at follow up is influenced by certain participant characteristics and attrition is non-random, thus influencing results and meaning that these are not representative of the intended population (Munafò et al., 2017). The reduced sample number at follow up may also influence findings where it becomes more difficult to distinguish whether there is a true effect.

Unfortunately, three of the five studies reviewed did not report information on their attrition rates and how they accounted for missing data in their studies, hence, it is difficult to judge bias of the findings due to attrition. Hall et al. (2014) reported high attrition rates ranging from 15.9% for unadjusted analyses to 36.8% for adjusted analyses. They did not report on reasons for missing-ness but did use a prorating method where there were missing OME and hearing data and only a minimal difference in effect size was found. However, there was no report of how they accounted for missing outcome data.

Bennett et al. (2001) followed up participants at the most time points and reported low attrition rates, however, they only reported on how many subjects had full otological data at each age and not outcome data. They also did not report reasons for missing data. Roberts et al. did not report any loss

to follow up. Outcome data was obtained through data linkage for Augustsson and Engstand (2001) who reported the number of children for whom outcome data was available but not how many of these children were included in analyses as well as any efforts of trying to study who linked data was not available for. Lous (1993) reported that of their original cohort of 387 children, 9 had moved out of the area, 3 had changed grades and 9 were absent on the day of assessment. Although this was only 5% of the cohort, bias may be present in the direction of absence from school being health related and linked to poorer performance (Allison and Attisha, 2019; Pijl et al., 2021).

4.3.1.5.3 Detection bias

Detection bias denotes the presence of systematic differences between groups in how outcomes are determined (Sterne et al., 2020) and can arise when investigators are aware of the exposure group that subjects belong to which influences the outcome assessment, therefore invalidating the study results. Efforts to reduce detection bias were made by Roberts et al., as outcome assessors were blind to the child's hearing status. This was also the case for Hall et al. (2014) and Bennett et al. (2001). As linked data to educational achievement grades were used by Augustsson and Engstand (2001), this was also avoided here. Lous (1993) did not report on whether assessors were blinded to the child's otological status.

4.3.1.5.4 Confounding

A major consideration when interpreting the findings of these studies is the extent to which they have controlled for confounding. Confounding is present when there are common causes of exposure and outcome and can result in the association between the exposure and outcome differing from its causal

effect, thus overestimating any effect (Sterne et al., 2020). Potential confounders of the relationship between OME and cognitive/academic ability which should be considered in analyses include sex of the child, craniofacial defects, ethnicity, socioeconomic background, maternal education and parental smoking habits (see Chapter 7 for a discussion of these factors).

Lous (1993) did not run an adjusted analysis, controlling for confounding after finding that there was no association between HL and reading achievement after running their unadjusted analysis. All other studies accounted for sex of the child. Socioeconomic factors were controlled for by all studies apart from that by Augustsson and Engstand (2001). Augustsson and Engstand (2001) did not control for socioeconomic factors so differences found which almost reached significance in their study may be due to this residual confounding as they did not report the socioeconomic characteristics of the sample.

Bennett et al. (2001) accounted for socioeconomic status (SES) and found that socioeconomic background was more closely related to cognitive development and academic ability. Hall et al. (2014) adjusted for maternal education and SES and did not find a marked effect, however, their sample size was mostly socially advantaged. Roberts et al. controlled for socioeconomic factors such as living in poverty and maternal education, though, their sample consisted mostly of socially disadvantaged children from low income families.

Sex and socioeconomic factors were the most common confounders accounted for by the different studies. Only Hall et al., (2014) considered parental smoking habits. They included maternal smoking in pregnancy in their adjusted analyses which showed only a slight difference in effect sizes. Details on whether any of the children had congenital defects such as craniofacial abnormalities were not given by any of the studies, apart from Roberts et al. who reported that none of the children had any medical issues. As a group more prone to developing OME and performing more poorly in academia, children who had any craniofacial abnormalities would have to be specified (Shott et al., 2001; Sheahan et al., 2002). Augustsson & Engstand did control for days spent in hospital to indicate any

other health issues and reported an association with days spent in hospital and low grades in Swedish only. They studied days spent in hospital as a confounder as they reported that general poor health could be associated with both OM and low grades.

Covariates (factors associated with the outcome only) included in analyses by Roberts et al. and Hall et al. (2014) were in relation to the quality and responsiveness of home and care environments and parenting style. These were not confounders but can be important to consider when studying the magnitude of the influence of long-term OME related HL on cognition and academic ability. While Hall et al. (2014) specified that these factors were considered in interaction analyses, Roberts et al. did not specify whether these variables were treated differently to confounders. In fact, all other factors aside from the exposure and outcome variables were termed as covariates by Roberts et al. thus not making it clear whether confounding factors were treated as confounders or covariates in analyses which may reduce reliability of effect sizes.

4.3.1.5.5 Summary

Table 4.5 Summary of risk of bias rating for the five studies selected for review

Study	Exposed and non-exposed subjects drawn from same population	Assessment of exposure	Outcome of interest not present at start of study	Control for other factors	Assessment of confounders & covariates	Assessment of outcome	Follow up of cohorts adequate?	Overall risk of bias
Lous								
Augustsson & Engstand								
Bennett et al.								
Roberts et al.								

Hall et al.								

All studies except for Roberts et al. presented with a high risk of bias in at least one domain. These domains were those of confounding and attrition bias. The study by Lous (1993) has been rated as having a high risk of bias in relation to confounding as although they identified potential confounding factors, the analysis focusing on HL did not control for these. Furthermore, the outcome measure used was not age-specific to ascertain that the outcome was not present at the start of the study. Moreover, hearing was assessed on fewer occasions compared to middle ear functioning assessment, with Lous reporting that only 8% of children presented with HL lasting 3 months or longer, thereby inferring that the long-term OME related HL exposure possibly was not the main exposure in this study. Attrition, however, was low in this study.

Confounding bias was also rated as high in the studies by Augustsson and Engstand (2001) and Bennett et al. (2001) who only controlled for sex and general health and sex and SES, respectively. Hall et al. (2014) was rated high in respect to attrition bias due to the high rates of loss to follow up, as was Bennett et al. (2001) who did not report on attrition rates which are expected to be high as this was a longitudinal study assessing outcomes at four time points. Confounding and attrition are dominant issues with longitudinal studies as it is difficult to control for every factor and to manage loss to follow up. Roberts et al. studied a smaller sample size; hence these difficulties would not be as pronounced. Although attrition rates were not discussed, between the two Roberts et al. studies, the sample size differed by two inferring that loss to follow up at the later time point was two children. A greater range of ages was studied in the second study; with loss to follow up between these ages not mentioned so attrition may have been greater in this later study. From the small sample size and focused nature of the study, this is not likely but in this context the study may present with a medium risk of bias. As it is also not possible to completely control for confounding, the study presents with a medium risk of bias and out of the four studies reviewed is the highest of quality.

4.3.2 Study findings

Tables 4.6 and 4.7 display the results for each outcome from each study. Results in relation to IQ are presented first in Table 4.6, followed by those for spelling, reading, math skills, change over time, and grades in Table 4.7. As mentioned earlier in this chapter, due to the heterogeneity in how HL exposure was defined and the outcomes measured, a meta-analysis was not carried out.

4.3.2.1 IQ

Two of the prospective studies (Bennett et al., 2001; Hall et al., 2014) included in this review studied IQ as an outcome using the Wechsler Intelligence Scales for Children. Both studies found evidence of an association between IQ and long-term OME related HL.

The two studies differed in terms of the age of children studied and age of children when IQ was assessed. Both studies assessed verbal and non-verbal IQ and used linear regression to analyse the association between OME & HL and IQ, however results were reported as standardised partial beta coefficients by Bennett et al. (2001) and as unstandardised regression coefficients by Hall et al. (2014). Both were converted to represent the mean difference in IQ scores between children with and without long-term OME and HL and are presented in Table 4.6.

Figure 4.2 presents a visual representation of the mean differences at each age for verbal and non-verbal IQ. In Hall et al. (2014) mean differences in IQ decreased with age, however, in Bennett et al. (2001) mean difference in IQ increased with age. In both studies, the effect on verbal IQ was greater than the effect on non-verbal IQ and wider confidence intervals for non-verbal IQ were reported, particularly in Bennett et al. (2001).

Table 4.6 Mean difference in IQ points between children with and without long-term OME related HL – findings from Hall et al. (2014) and Bennett et al. (2001)

Authors	Measure of exposure	Outcome	Unadjusted mean difference in IQ points (95% CI)	p	Adjusted mean difference in IQ points (95% CI)	p value
Hall et al. 2014	Cumulative OME/HL history score between 8 months and 4 years grouped as 1 (no OME/HL) and 2 (highest 10% OME/HL scores)	Verbal IQ at 4 years	−7.38 (−10.59, −4.17)	<=0.001	−7.17 (−10.30, −4.03)	<=0.001
		Non-verbal IQ at 4 years	−5.9 (−9.41, −2.39)	0.001	−5.16 (−8.70, −1.62)	0.004
		Verbal IQ at 8 years	−3.98 (−8.42, 0.44)	0.078	−3.91 (−8.33, 0.50)	0.0826
		Non-verbal IQ at 8 years	−3.95 (−8.45, 0.55)	0.085	−3.77 (−8.46, 0.91)	0.115
Bennett et al. 2001	Cumulative OME history between 5 & 9 years grouped from 1 (always type A tymp in both ears) to 7 (bilateral tubes >1 occasion for OME with proven hearing loss)*	Verbal IQ at 11 years	-	-	−8.10 (-9.54, -6.71)	<0.01
		Non-verbal IQ at 11 years	-	-	−5.58 (-12.24, -4.50)	<0.001
		Total IQ at 11 years	-	-	−7.74 (-24.12, -4.14)	Not reported as significant
		Verbal IQ at 13 years	-	-	−12.96 (-14.90, -6.39)	<0.01
		Non-verbal IQ at 13 years	-	-	−9.99 (-24.48, -8.91)	<0.05
		Total IQ at 13 years	-	-	−12.96 (-32.31, -6.39)	<0.001

*originally grouped as 1) bilateral tubes >1 occasion for OME with proven hearing loss and 7) always type A tympanogram in both ears but for ease of comparison grouped as in table

Bennett et al.(2001) - no report on measures of variance such as standard deviation (SD), thus, as IQ is a standardised measure with a mean of 100 and SD of 15 (Franzen, 2000), calculations were made to convert the reported standardised beta coefficients into unstandardized coefficients. The reported standardised beta coefficients by Bennett et al. were multiplied by 15 (one SD) and then multiplied by 6 (to get from group 1: bilateral long-term OME & HL to group 7: always bilateral type A tympanogram). Confidence intervals were calculated in the same way.

Mean adjusted differences:
Hall et al. (2014) – adjusted for sex, birthweight, gestational age, maternal education level, housing tenure, parental social class, maternal age, parity and smoking during pregnancy
Bennett et al. (2001) – adjusted for sex and socioeconomic status.

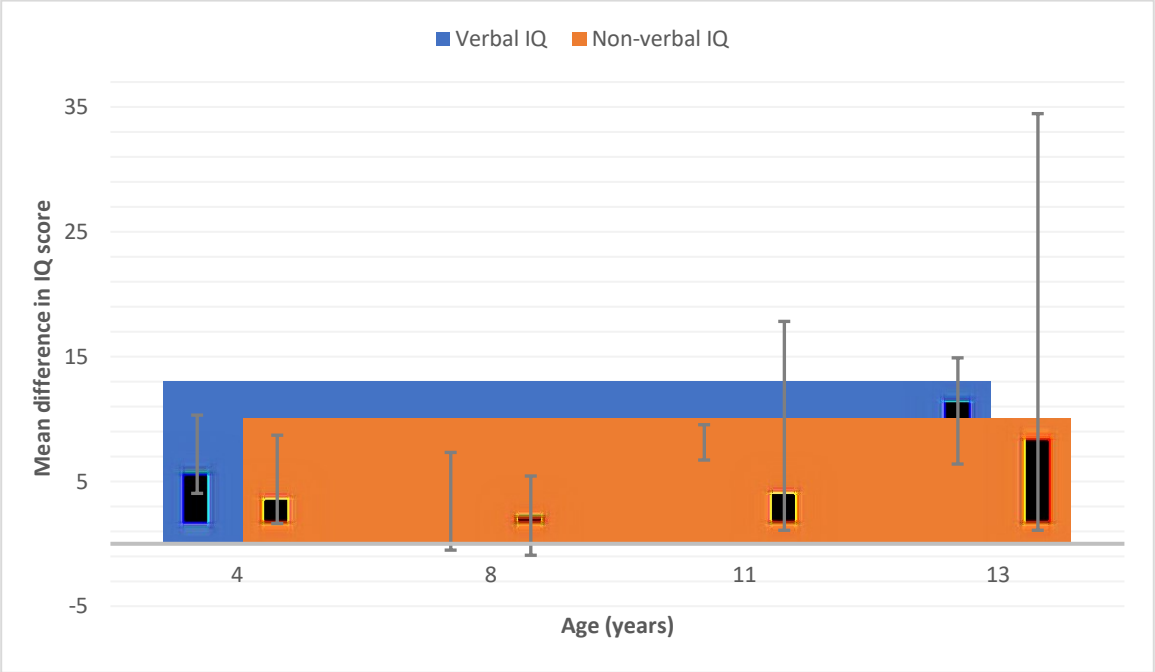


Figure 4.2 Adjusted mean differences in IQ with 95% confidence intervals from Hall et al. (4 & 8 years) and Bennett et al. (11 & 13 years) indicating the reduction in IQ points presented by children with long-term OME related HL

4.3.2.2 Academic outcomes

Table 4.7 displays the results pertaining to academic outcomes from all five papers.

Means and standard deviations were not reported by Bennett et al. for academic outcomes to calculate the difference in mean scores between those with and without long-term OME and HL as they were for IQ scores. Associations between long-term OME related HL and spelling at 11 and 13 years, reading at 11, 13, 15 and 18 years and math skills at 5 years were reported. Roberts et al. (2002) also studied change in ability over time for reading and math skills using general linear mixed models and reported a significant association with math skills where children with HL performed more poorly at younger ages but caught up once they started school.

Bennett et al. (2001) also performed a repeated measures analysis on reading scores, as data for reading was available at four time points. However, they did not report the statistic for change over

time and reported qualitatively that after adjustment for sex and SES, there was a marginal association between ear status at age 9 and mean reading scores with a p value of 0.054.

The findings from all four studies present weak to moderate associations with early long-term OME related HL and math skills in early childhood and later long-term OME related HL and spelling and reading skills in the adolescent period. Significant associations between long-term OME related HL and reading ability in early childhood and between later long-term OME related HL and standardised grades were not reported.

Table 4.7 Results of analyses of long-term OME related HL and academic outcomes from the four studies selected for review which studied academic outcomes

Outcome	Study	Statistical analysis	Measure of exposure	Outcome	Effect size	P	Notes on effect size
Spelling	Bennett et al. (2001)	Linear regression	Cumulative OME history between 5 & 9 years grouped as: 1) Bilateral tubes >1 occasion for OME and proven hearing loss 2) Bilateral persistent OME with or without VT but no evidence of HL exceeding 25 dB on at least one occasion 3) Unilateral persistent OME with or without VT on at least one occasion 4) Transient unilateral or bilateral OME on at least one occasion 5) No evidence of OME but scar tissue present 6) C tympanogram on at least one occasion but no OME or type B tympanogram 7) Always type A tympanogram in both ears	Score on Dunedin spelling test at age 11	0.090 (0.016-0.165)	<0.05	Standardised partial beta coefficient adjusted for sex and socioeconomic status where a value of 0.1 or greater indicates a moderate association. Values in parentheses represent 95% confidence intervals. Effect size indicates a weak association.
		Linear regression	Cumulative OME history between 5 & 9 years grouped as 1-7 as described above	Score on Dunedin spelling test at age 13	0.115 (0.044-0.186)	<0.01	Standardised partial beta coefficient adjusted for sex and socioeconomic status where a value of 0.1 or greater indicates a moderate association. Values in parentheses represent 95% confidence intervals.

							Effect size indicates a moderate association.
Reading	Roberts et al. (2000)	Linear regression	Total HL (percentage of days) between 6 months and 4 years	Score on Letter Word Identification subtest from the WJPB at 5 years	-0.05 (0.05)	Not reported as significant	Regression coefficient adjusted for gender, whether family lives in poverty, maternal education, quality of home environment and quality of childcare environment Value in parentheses represents the standard error. Effect size is close to zero indicating no association.
	Roberts et al. (2002)	Pearson correlations	Total HL (percentage of days) between 6 months and 4 years	Score on Letter Word Identification subtest from the WJPB at 5 years	-0.07	Not reported as significant	Correlation coefficient adjusted for child's gender, home environment and maternal education. No correlation.
		Pearson correlations	Total HL (percentage of days) between 6 months and 4 years	Score on Letter Word Identification subtest from the WJPB at 6 years	0.00	Not reported as significant	Correlation coefficient adjusted for child's gender, home environment and maternal education. No correlation.
		Pearson correlations	Total HL (percentage of days) between 6 months and 4 years	Score on Letter Word Identification subtest from the WJPB at 7 years	-0.15	Not reported as significant	Correlation coefficient adjusted for child's gender, home environment and maternal education. No correlation.
		Pearson correlations	Total HL (percentage of days) between 6 months and 4 years	Score on Letter Word Identification subtest from the WJPB at 8 years	0.02	Not reported as significant	Correlation coefficient adjusted for child's gender, home environment and maternal education. No correlation.

		General linear mixed model	Total HL (percentage of days) between 6 months and 4 years	Development of letter word identification (reading) skills overtime (WJPB) (prekindergarten to Grade 2: 5 to 8 years)	-0.00 (0.02)	Not significant	Regression coefficient for quadratic change in reading skills overtime. No association.
	Lous (1993)	Linear regression	Mean hearing threshold from 5 screenings carried out	Score on OS-400 Silent reading test at age 8	0.06	0.48	Standardised beta regression coefficient. No association between mean hearing threshold and reading score.
	Bennett et al. (2001)	Linear regression	Cumulative OME history between 5 & 9 years grouped as 1-7 as described above	Score on Burt reading test at age 11	0.099 (0.0245-0.174)	<0.01	Standardised partial beta coefficient adjusted for sex and socioeconomic status where a value of 0.1 or greater indicates a moderate association. Values in parentheses represent 95% confidence intervals. Effect size indicates a moderate association.
		Linear regression	Cumulative OME history between 5 & 9 years grouped as 1-7 as described above	Score on Burt reading test at age 13	0.116 (0.045-0.187)	<0.01	Standardised partial beta coefficient adjusted for sex and socioeconomic status where a value of 0.1 or greater indicates a moderate association. Values in parentheses represent 95% confidence intervals. Effect size indicates a moderate association.

		Linear regression	Cumulative OME history between 5 & 9 years grouped as 1-7 as described above	Score on Burt reading test at age 15	0.115 (0.050-0.180)	<0.01	Standardised partial beta coefficient adjusted for sex and socioeconomic status where a value of 0.1 or greater indicates a moderate association. Values in parentheses represent 95% confidence intervals. Effect size indicates a moderate association.
		Linear regression	Cumulative OME history between 5 & 9 years grouped as 1-7 as described above	Score on Burt reading test at age 18	0.112 (0.047-0.177)	<0.01	Standardised partial beta coefficient adjusted for sex and socioeconomic status where a value of 0.1 or greater indicates a moderate association. Values in parentheses represent 95% confidence intervals. Effect size indicates a moderate association.
Maths	Roberts et al. (2000)	Linear regression	Total HL (percentage of days) between 6 months and 4 years	Score on Applied Problems subtest from the WJPB at 5 years	-0.15 (0.05)	<0.01	Regression coefficient adjusted for gender, whether family lives in poverty, maternal education, quality of home environment and quality of childcare environment Value in parentheses represents the standard error. Effect size indicates a small negative association between

							increasing amount of HL and score for math skills.
	Roberts et al. (2002)	Pearson correlations	Total HL (percentage of days) between 6 months and 4 years	Score on Applied Problems subtest from the WJPB at 5 years	-0.33	<0.01	Correlation coefficient adjusted for child's gender, home environment and maternal education. Effect size indicates a negative correlation between increasing amount of HL and score for math skills
		Pearson correlations	Total HL (percentage of days) between 6 months and 4 years	Score on Applied Problems subtest from the WJPB at 7 years	-0.11	Not reported as significant	Correlation coefficient adjusted for child's gender, home environment and maternal education. No correlation.
		Pearson correlations	Total HL (percentage of days) between 6 months and 4 years	Score on Applied Problems subtest from the WJPB at 8 years	-0.19	Not reported as significant	Correlation coefficient adjusted for child's gender, home environment and maternal education. No correlation.
		General linear mixed model	Total HL (percentage of days) between 6 months and 4 years	Development of Applied problem (maths) skills overtime (prekindergarten to Grade 2: 5 to 8 years)	-0.03 (0.01)	<0.05	Regression coefficient for quadratic change in reading skills overtime. Children with more HL between 6 months and 4 years had more difficulty with the development of math skills overtime. This was more so at the younger ages and children were seen to catch up with peers once they had started school.

Standardised grades	Augustsson and Engstand (2001)	Linear regression	Cumulative history of SOM during first 14 years of life grouped into: 1) Healthy - No contact with the ENT clinics and no treatment at the age of 0–14 years 2) Treated SOM	Mean of grades (English, Mathematics, Swedish) at 15/16 years	-0.128	0.051	Regression coefficient after adjusting for sex and days in hospital (general health) No association.
		Logistic regression	Cumulative history of SOM during first 14 years of life grouped into: 1) Healthy - No contact with the ENT clinics and no treatment at the age of 0–14 years 2) Treated SOM	Proportion of low grades in English at 15/16 years	1.2325	0.3777	Odds ratio adjusted for sex and days in hospital (general health). No association.
		Logistic regression	Cumulative history of SOM during first 14 years of life grouped into: 1) Healthy - No contact with the ENT clinics and no treatment at the age of 0–14 years 2) Treated SOM	Proportion of low grades in Mathematics at 15/16 years	1.0657	0.7853	Odds ratio adjusted for sex and days in hospital (general health) No association.
		Logistic regression	Cumulative history of SOM during first 14 years of life grouped into: 1) Healthy - No contact with the ENT clinics and no treatment at the age of 0–14 years 2) Treated SOM	Proportion of low grades in Swedish at 15/16 years	0.9309	0.7824	Odds ratio adjusted for sex and days in hospital (general health). No association.

4.4 Discussion

The scientific literature on the impact of long-term OME related HL on children's cognition and academic ability was systematically searched and reviewed. Five prospective studies were deemed eligible and were selected for review. IQ was measured by two of the studies, with the remaining studies focusing on academic ability.

While associations were reported with various academic outcomes and IQ, each study reviewed presented with a medium level of bias. The study by Roberts et al. seemed to be the most robust out of the five studies reviewed. Both longitudinal birth cohort studies were rated as having a medium risk of bias, due to potential bias through attrition and selection bias, though with this study design bias is difficult to avoid. Lack of reporting by Augustsson and Engstand (2001) makes it difficult to draw a conclusion about the reliability of their findings. Due to the small number of children found to have a long-term HL in the study by Lous (1993), the finding from this study is not reliable and thus will not be considered.

Although the majority of studies focused on academic measures, the evidence for an association with IQ appears to be more reliable compared to the weaker evidence for an association with academic skills. While Roberts et al. only reported a significant association with math skills which was attenuated in later childhood, Bennett et al. (2001) provided evidence for an association between spelling and reading abilities at later ages. Furthermore, both studies that looked at IQ reported negative associations with IQ at both younger and later time points. Interestingly, Hall et al., also reported an association with IQ that was present at the younger age but diminished at a later age of 8 years. These findings may generally suggest that long-term OME related HL may influence cognition and academic ability in early childhood, but not at later ages. However, the differences in IQ and scores on academic measures reported by Bennett et al. (2001) were not only found at ages above 8 years but were also found to increase with age into the teen years.

There are a few points to consider when interpreting these findings. The first being the ages at which long-term OME and HL was studied. Hall et al. (2014) studied children with cumulative OME/HL histories between 8 months and 4 years, whereas Bennett et al. (2001) studied children with cumulative OME/HL histories during later childhood, between 5 and 9 years. This itself could potentially explain the difference in trend between the two studies. Assuming that the OME and HL experienced by children in Hall et al.'s study cleared up beyond the age range studied, children may not have displayed negative effects in IQ four years later as the HL may have resolved within potential sensitive periods of development. This would have allowed children to develop to their potential once the HL had resolved, also owing to auditory plasticity following the resolution of CHL, as discussed in Chapter 2.

Conversely, in the study by Bennett et al. (2014) the greatest differences in IQ were at age 13, and instead of showing an improvement with age, the difference increased with age, despite potential attrition and a reduction in power to detect a difference. These findings contradict the findings by Hall et al. (2014) which showed an improvement with age. However, the period in which OME related HL was experienced in the study by Bennett et al., (2001) was at a later stage. HL experienced in Bennett et al.'s study was likely longer-lasting and as a result children may not have been as able to take advantage of neural plasticity, which may explain why their IQ scores were poorer than those without long-term OME related HL at these ages. Furthermore, although IQ is generally thought to remain stable across the life span, shifts in IQ as children enter adolescence due to changes in brain structure, have been reported (Ramsden et al., 2011). In addition, more recently, it has emerged that adolescence may characterise a sensitive period of brain development (Fuhrmann et al., 2015). However, this sensitive period is characterised by individual differences. Differences in IQ in older children and adolescents have been found between those with different environmental conditions (Makharia et al., 2016; Ghazi et al., 2012). These include mental stress, access to public services, place of residence, physical activity, family income, parental education and

occupation of the father. Although Bennett et al adjusted for SES, other factors may have moderated the associations, however, from the reported findings this is not clear.

The difference in timing of exposure can also apply to the academic outcome findings. In Roberts et al.'s study, OME and HL was experienced between 6 months and 4 years in line with sensitive periods, with outcomes measured at ages 5-8 years. Associations with reading skills were not found at any of these ages, yet Bennett et al. reported associations with reading ability at ages 11, 13, 15 and 18. Roberts et al.'s analysis overtime however, showed that there was a small negative association with maths skills which diminished with age. Bennett et al. did not study math skills in order to compare this finding with math skills at later ages. Nevertheless, Augustsson & Engstand (2001) studied the association between long-term OME related HL between the ages of 4 and 14 years and math grade at age 15/16 for which no association was reported. Having said this, it is important to note that grades as an outcome differ from IQ and assessments of academic skills and ability such as reading, spelling and math skills. While assessment of IQ and these skills and abilities require no preparation, grades are based on assessments for which children prepare for over long periods of time and may receive help with this preparation from teachers, parents and siblings. Therefore, even if their IQ or abilities are poorer, if they make consistent effort to learn and pass assessments, they may still be able to score at the same level as their peers. As reported by Neisser et al. (1996) the achievement of good grades depends on an array of factors other than IQ, including persistence, interest in school and a willingness to study. In the case of this study, grades were formed of marks from national standardised exams and marks from schoolwork as well as teachers report of classroom behaviour and attitude, so provide a more overall grade of school performance.

What's more, in relation to timing of exposure, although Augustsson & Engstand (2001) looked at whether children had ventilation tubes inserted for every 2-year period, they did not report any information on when the children in the treated group had these inserted and how many insertions were made. It would be useful to know when tube insertion took place, as an indication of when the

children experienced long-term OME related HL, as we have seen from the other prospective studies that impact of long-term OME related HL may differ with timing of experience and the ages at which outcomes are studied.

The findings from this review provide evidence of an association between long-term OME related HL and IQ. This association is present when long-term OME related HL is experienced in both early childhood and later childhood, with outcomes affected into adolescence, which suggests that long-term OME related HL may have an impact across the life course. The evidence for an association with academic ability is inconsistent. This may be due to the heterogeneity in the outcome measures used in each study, along with the timing of exposure. One study provided data on educational measures in early childhood, from which an association with math skills was found with no associations with reading ability. This is interesting as long-term OME related HL was found to be more strongly linked with verbal IQ. Nonetheless, the mathematical skills were assessed verbally so would require the use of a greater range of cognitive domains. Bennett et al. (2001) provided much of the data on outcomes in adolescence, from which associations were reported. Nevertheless, although this study accounted for two important confounding factors, this was a limited range and residual confounding may be present. For example, SES is a strong predictor of both health and educational achievement and the grouping is usually based on information relating to the father and not the mother. However, the educational level of the mother has been reported to be more closely linked to outcomes, thus should also be considered (Dickson et al., 2016; Harding et al., 2015). Further research on later long-term OME related HL and outcomes into adolescence is required to provide stronger evidence.

4.4.1 Limitations of this review

Limitations of this systematic review include the presence of selection bias through language as studies not written in English were not considered for review. More so, only published studies were included and searches for unpublished studies were not made, hence publication bias may be present. Furthermore, this review can be criticised for limiting the measure of cognitive development to intelligence quotient, however a consistent measure of cognition allowed associations to be seen more clearly.

4.5 Chapter summary

This chapter described a systematic review of the current literature on the impact of long-term OME & HL on children's cognitive development and academic ability, focusing on studies of the best quality. While this review addressed concerns raised by previous reviews, suggesting that differences in OME exposure definition between studies and failure to account for associated HL as well as differences in study design contributed to the inconsistency in findings, weak evidence of a negative association between long-term OME & HL and cognition and measures of academic ability across childhood and adolescence was presented. This review uncovered that even whilst focusing on more persistent cases of OM & HL, evidence for an association between OM related HL and cognition and academic ability is fairly weak and thus more research is needed. The study of OME and HL and outcomes at different ages in childhood and adolescence between studies and the inconsistency in control for confounding renders it difficult to draw reliable conclusions and further research studying long-term OME related HL and associations with outcomes overtime whilst controlling for confounding is required.

The following chapters address research carried out to further investigate long-term OM related HL and its impact on developmental outcomes using data from a longitudinal birth cohort study. The next chapter introduces this study.

Chapter 5. Introduction to the Avon Longitudinal Study of Parents & Children

5.1 Introduction

This chapter introduces the Avon Longitudinal Study of Parents and Children (ALSPAC). The background to ALSPAC is detailed, followed by an account of the data collected by ALSPAC to inform the reader why the ALSPAC dataset was deemed to be suitable for investigating the prevalence and impact of long-term OM related HL. The chapter concludes with a brief outline of the strengths and limitations of ALSPAC.

5.2 Background to ALSPAC

The Avon Longitudinal Study of Parents and Children (ALSPAC) is a large, world leading prospective birth cohort study based in the UK, which studies the environmental and genetic factors that affect a person's health and development across the life course (Boyd et al., 2013); University of Bristol http://www.bristol.ac.uk/alspac/about/). 14,541 pregnant women residing in the Avon area in the UK between 1991-1992 were recruited to take part in this study. These women, the children they gave birth to and their partners have intensively been followed up since then (Boyd et al., 2013).

Data in ALSPAC are available on a range of genetic, biological, psychological, social and environmental exposures. Data on educational, health, social and developmental outcomes are also

available. Examples of this data include, blood and urine samples, hair and nail samples, data on weight and height, diet, exercise, vision, hearing, general health, mental health and socioeconomic factors (Boyd et al., 2013). In addition, data on the parents of the children involved in the study are accessible (Golding et al., 2001). These data have been collected at multiple time points through various measures such as biological resources, questionnaires completed by mothers, their partners, the child and schools, and focus clinic assessments, as well as through linkage to educational and medical records (Boyd et al., 2013; University of Bristol, 2017).

5.2.1 Selection of ALSPAC cohort

All pregnant women residing in the county formerly known as Avon with a delivery date falling between April 1991 and December 1992 were eligible and invited to take part in ALSPAC. This area was also part of the South West Regional Health Authority (now Bristol & District Health Authority) and included the city of Bristol and surrounding areas but not the city of Bath. Both urban and rural areas were included and consisted of towns, villages and farming communities (Boyd et al., 2013). Pregnant women who moved into the area up to the point of delivery were included in the sample. Pregnant women who were originally living in Avon but were migrating out of the area were not included in the sample unless they had completed a questionnaire sent to them during their third trimester. A small selection of individuals (229 pregnant women giving birth to 233 children) who did not meet this eligibility criterion were included in the sample due to them having already enrolled and provided data (Boyd et al., 2013).

Recruitment took place through opportunistic sampling and the aim was to recruit women early in pregnancy. The study was advertised in the media and recruitment staff made visits to community locations. The study was also promoted through routine antenatal and maternity health services. These services distributed an ‘expression of interest’ card. By returning this card, women were able

to express their interest in the study and request further information or decline participation in the study. Eligibility was assessed through the returned completed cards and a study information booklet was sent to eligible women who had expressed interest in participation. One week later, a questionnaire was sent to them. Study consent was 'opt out' whereby if women did not actively decline participation, they were included in future data collection follow up (Boyd et al., 2013).

The known eligible sample comprised of 20,248 pregnancies, of which 14,541 were recruited. 13,988 of these pregnancies were alive at 1 year. There were further recruitment phases where it was attempted to recruit known eligible children who would have fitted the eligibility criteria but from who there was no contact antenatally. These phases occurred when participants were around 7 (phase II) and 8 years onwards (phase III) where they were invited to follow up assessment clinics. 452 children were recruited at age 7 and 254 at age 8 (Boyd et al., 2013). ALSPAC has continued to enrol participants and now has data on 15,645 children.

5.2.2 Representativeness of sample

Children living in Avon were found to be similar to the rest of the children in terms of many characteristics (Golding et al., 2001). They were as likely as those from the rest of Great Britain to be living with a single parent at the age of 5 years, as likely to have a non-European Caucasian parent, as likely to have a parent with a University degree and as likely to be living in an apartment or rooms. However, they were significantly less likely to be living in rented accommodation and to have a father in a manual occupation. There were no differences in parental smoking levels and similar proportions of children were living in rural areas. There were also no significant differences in preterm deliveries of babies, low birthweight, physical or mental disability and problems with speech, vision or behaviour. As there were few differences found, the ALSPAC sample was concluded to be quite similar to the rest of Great Britain.

Later analyses using the 1991 census compared the socio-economic characteristics between mothers of infants <1 year of age living in Avon with mothers of infants <1 year in the whole of Britain. Also, data collected from an ALSPAC questionnaire completed by mothers 8 months after the birth of their child was used to compare ALSPAC mothers with mothers in Avon in general (Fraser et al., 2013). The questionnaire was completed by 80% of mothers enrolled in ALSPAC so comparisons for lack of response were also made. Avon mothers were more likely to live in owner-occupied accommodation and have a car and were less likely to have one or more persons per room and be non-White. A similar number of women in Avon and in rest of Britain were married.

However, ALSPAC mothers were more likely to be living in overcrowded conditions than mothers in Avon not involved with ALSPAC. Having said this, ALSPAC mothers were more likely than mothers in Britain and mothers in Avon in general to live in owner-occupied accommodation, to have a car, to be married and were less likely to be non-White (Fraser et al., 2013). Accordingly, the ALSPAC cohort is seen to be slightly more socially advantaged than the rest of the UK in general.

5.2.3 Missing data

The extensiveness of repeated measures at regular intervals across the life course is one of the defining features of the ALSPAC study. However due to loss to follow up, data is not available for every participant at each time point. Attrition has been reported to be lowest when the child was in infancy and has found to have increased upon entering adulthood. Although there is permanent attrition present, analysis of response rates suggests that this is down to selective participation. To provide a picture of response rates, while an average of 6,155 of the cohort responded to all 12 measures during the adolescence phase, 9,600 responded at least once during this phase; and a sub-sample of over 3,000 families had responded to all 55 assessments administered up until the age of 18 years (Boyd et al., 2013). ALSPAC has tried to limit loss to follow up by sending out reminders and

actively encouraging completion of questionnaires and attendance at assessments. For example, during pregnancy mothers were sent questionnaires to be completed. A reminder letter was sent to mothers if a response was not received within 7 days. If after this, a response was still not received after a further 10 days, a second reminder letter was sent. If a further month had gone by with no response, a member of the ALSPAC team had rang the mother or visited her to encourage her and aid her in completing the questionnaire (Golding et al., 2001).

5.3 Data collection in ALSPAC

A range of sources were designed to obtain information starting from early pregnancy (Boyd et al., 2013). These are listed in Table 5.1.

Table 5.1 List of data collection sources used in ALSPAC

Self-completion questionnaires for mothers, their partners, children from age 5 onwards and their teachers
Medical & educational records
For sub-samples of homes - measurements of the environment including levels of air pollutants, magnetic radiation and noise
For a randomly selected 10% of the sample (CiF) – hands on assessment at frequent intervals from ages 4 months to 5 years
In-depth interviews and examination of particular sub-groups and their controls
Annual hands-on assessments of the whole cohort in a standardised environment from 7 years onwards
Biological samples from the mother, her partner and child

Data obtained from the questionnaires, linkage to medical and educational records and hands-on assessments are of importance to this thesis. These methods are described below with information regarding the hearing data obtained. Chapter 7 reports on the data on selected outcome measures studied in this thesis in more detail.

5.3.1 Self-report questionnaires

Questionnaires have been used throughout the study to collect information on phenotypical and environmental measures (Boyd et al., 2013). Table 5.2 below displays the type of information collected about the child through questionnaires.

Table 5.2 Data on the child collected through self/parent/teacher reports via questionnaires in ALSPAC

Measure of	**Information collected**
Demographics	Ethnicity
Health	Morbidity, accidents and injuries, medication, supplements and treatments
Psychological & social factors	Alcohol, smoking and illicit drug use, sexual behaviour, depression, significant life events, parent peer and sibling relationships, peer networks, temperament and behaviour
Development	Puberty and menstruation, speech and language, fine and gross motor coordination
Education	Understanding of mathematics and science, spelling, school experiences and aspirations, teacher assessment of the child
Diet	Food frequency
Housing	Type of home, tenure, number of rooms, availability of facilities (hot running water, central heating)
Social background	Social class based on parental occupations, parental educational level, type of neighbourhood, use of car
Household composition	Changes over time, crowding (person/room), pets
Stressors	Acute (measured with life events), conflict in the home, bullying/victimization at school, parental anxiety and depression
Air pollutants	Exposure to cigarette smoking, use of chemicals in the home, proximity to heavy traffic, types of heating and cooking at home, ventilation
Noise	Exposure at home and school

Physical environment	Time spent outdoors, methods of getting to school, time spent on various activities including watching TV
Safety	Safety equipment and measures taken at home
Type of school	School environment, day care, out of school care, school choice

Questionnaires were also used to obtain information in relation to these areas about the mother and her partner, along with additional information on maternal age, parity, family health, childhood health, and the mother's feelings about becoming pregnant and about becoming a mother and her reproductive health.

Four questionnaires were sent to mothers to complete at specific points in their pregnancy. These were sent to obtain information on the mother's health, home environment and lifestyle, ethnicity of the child, socioeconomic group (SEG), parental education, parental smoking and parental mental health. Further questionnaires were administered to mothers and their partners throughout childhood to obtain later information on health, environment and lifestyle and smoking habits.

5.3.2 Linkage to medical and educational records

ALSPAC has linkage to all medical records in relation to the pregnancy and child, given that there is no refusal from the mother. Relevant detailed obstetric information has been abstracted from paper records.

There is also access to educational records unless the mother has objected to this. This includes data on school entry tests and national attainment tests that all publicly funded, and some fee-paying schools administer (Golding et al., 2001).

5.3.3 Hands on assessment “focus” clinics

From the age of seven, all children in the ALSPAC cohort were invited to attend focus clinics at the University of Bristol. These were half-day assessments where clinical measures including measures of physical and physiological health, mental health, cognition, speech and language and social development were taken. These assessments included hearing assessments at ages 7, 9, 11 and 15 years (Boyd et al., 2013; Golding et al., 2001).

5.3.3.1 Hearing assessments

Hearing levels were measured for children who attended clinic sessions at University of Bristol at ages 7, 9, 11 and 15 using Pure Tone Audiometry. Air conduction (AC) thresholds were measured at 0.5-8kHz and bone conduction (BC) thresholds were measured at 0.5-4kHz according to the British Society of Audiology recommended procedure for audiometry (BSA, 2018). At age seven, Kamplex AD12 and GSI 61 audiometers were used and at ages 9, 11 and 15, GSI 61 audiometers were used. TDH 39 headphones, calibrated to ISO 389 were used at all ages (ISO389-1, 1998). While hearing assessments were carried out in a quiet room at age 7, at age 9, 11 and 15 they were conducted in sound treated booths. All tests were carried out by qualified audiologists or testers specially trained for this purpose who undertook regular audits to assess their reliability on audiometry. Testers were blinded to the results of previous hearing tests when performing audiometry.

Tympanometry, an assessment used to analyse middle ear function and routinely used to diagnose OM was carried out at ages 7-11 years (BSA, 2013). A Kamplex AT2 tympanometer was used at age 7 and a GSI 38 tympanometer at age 9 and 11 years according to BSA guidelines (BSA, 2013). However,

as the tympanogram classification can differ even in the presence of OM related HL, only hearing levels will be considered when determining the exposure group.

The measures of hearing make ALSPAC the largest longitudinal study in the world to have obtained repeated objective hearing measures, thereby making it the most suitable dataset to study long-term OM related HL. As identified in Chapters 2 and 4, large longitudinal population studies with repeated measures of hearing are required to help fill gaps in knowledge regarding long-term OM related HL.

5.4 Description of hearing data in ALSPAC

Although the ALSPAC dataset contains data on 15,645 children, data on hearing levels are not available for all of these children. As mentioned above, all children were invited to attend focus clinics from the age of seven at which hearing was assessed. Hence, information on hearing was only available for those children who attended each clinic. This section describes the hearing data obtained in ALSPAC at each time point.

5.4.1 Hearing assessment

The dataset included hearing thresholds for each individual frequency tested at each age for each child. Air conduction (AC) was tested at 500Hz, 1000Hz, 2000Hz, 4000Hz and 8000Hz at ages 7, 9 and 11. Bone conduction (BC) was tested at 1000Hz and 4000Hz at age 7 and at 500Hz, 1000Hz and 2000Hz at ages 9 and 11. At age 15, AC was tested at 1000Hz and 4000Hz and BC was not tested.

Table 5.3 summarises the number of children who had their hearing tested at each frequency for AC and BC for each ear at each age as well as the number of children with any available hearing data and those with missing hearing data at each time point.

Table 5.3 Number of children with hearing data at each frequency for the right ear (R), left ear (L), bone conduction testing (BC), any hearing data for any ear and number of children with missing hearing data. N/T = not tested.

Hearing data	**Time point (years)**				
		7	**9**	**11**	**15**
500 Hz	R	7,441	7,255	7,009	N/T
	L	7,434	7,255	7,011	N/T
	BC	N/T	7,110	7,034	N/T
1000 Hz	R	7,758	7,370	7,076	4,724
	L	7,756	7,368	7,073	4,727
	BC	7,569	7,325	7,042	N/T
2000 Hz	R	7,681	7,368	7,070	N/T
	L	7,678	7,366	7,072	N/T
	BC	N/T	7,126	7,035	N/T
4000 Hz	R	7,754	7,367	7,065	4,729
	L	7,752	7,364	7,061	4,730
	BC	7,701	N/T	N/T	N/T
8000 Hz	R	7,720	7,221	7,025	N/T
	L	7,709	7,215	7,030	N/T
	BC	N/T	N/T	N/T	N/T
Any hearing data		7,761	7,371	7,078	4,730
Missing data		7,884	8,274	8,567	10,915

As expected, due to most children experiencing fatigue and lack of concentration during BC testing, which takes place after testing of AC thresholds, the number of children with recorded BC thresholds was lower than the number with recorded AC thresholds at each age. The number of children with recorded thresholds at each frequency for AC and BC varied. For both AC and BC, thresholds at 1000Hz were obtained for a higher number of children than thresholds at the other frequencies. This makes sense as 1000Hz is the frequency that is usually first tested in audiometry as recommended by the British Society of Audiology (British Society of Audiology, 2018).

Therefore, in this thesis, the number of children who had their hearing assessed at each time point was determined as the number who had data recorded at 1000Hz for either the right or left ear. As

can be seen in Table 5.3, the number of children with hearing data decreased at each time point, with the largest decrease being at 15 years. While over 7,000 children attended the hearing assessments at the earlier time points, at age 15 this reduced to only 4,370 children.

5.4.2 Missing hearing data

The number of children with hearing data decreased at each time point. Although all participants were invited to the focus clinics where hearing assessments were carried out, a great number of children failed to attend, and the numbers of non-attendance increased with age.

These numbers indicate that at each time point, over half of the cohort did not have their hearing assessed. Table 5.4 summarises the number of children who did not attend any of the hearing assessments as well as the number of children who attended one, two, three or all four of the assessments. Of the whole cohort, 6,174 children did not have their hearing assessed at all. Only 3,483 children had their hearing assessed at all four-time points, which is less than a quarter of the cohort.

Table 5.4 Summary of hearing assessment attendance by children in ALSPAC

Number of clinics attended	Frequency
0	6,174
1	1,676
2	1,604
3	2,708
4	3,483

Figure 5.1 is a summary of clinic attendance by children in the ALSPAC cohort at each time point. The patterns of attendance are also displayed with the corresponding frequency count which represents the number of children who attended those specific clinics. It can be seen that the most attended

clinic was the 7-year clinic and the least attended clinic was at 15 years. As expected, attrition was greatest at the later time points. For children who attended two or three clinics, attendance was greater during consecutive clinics e.g. the numbers of children who attended at 7 & 9 and 9 & 11 were higher than the number of children who attended at 7 & 11 or 9 & 15. Similarly, for those who attended three clinics, the numbers of children who attended at 7, 9 & 11 and 9, 11 & 15 were higher than the number of children who attended at 7, 9 & 15 and 7, 11 & 15.

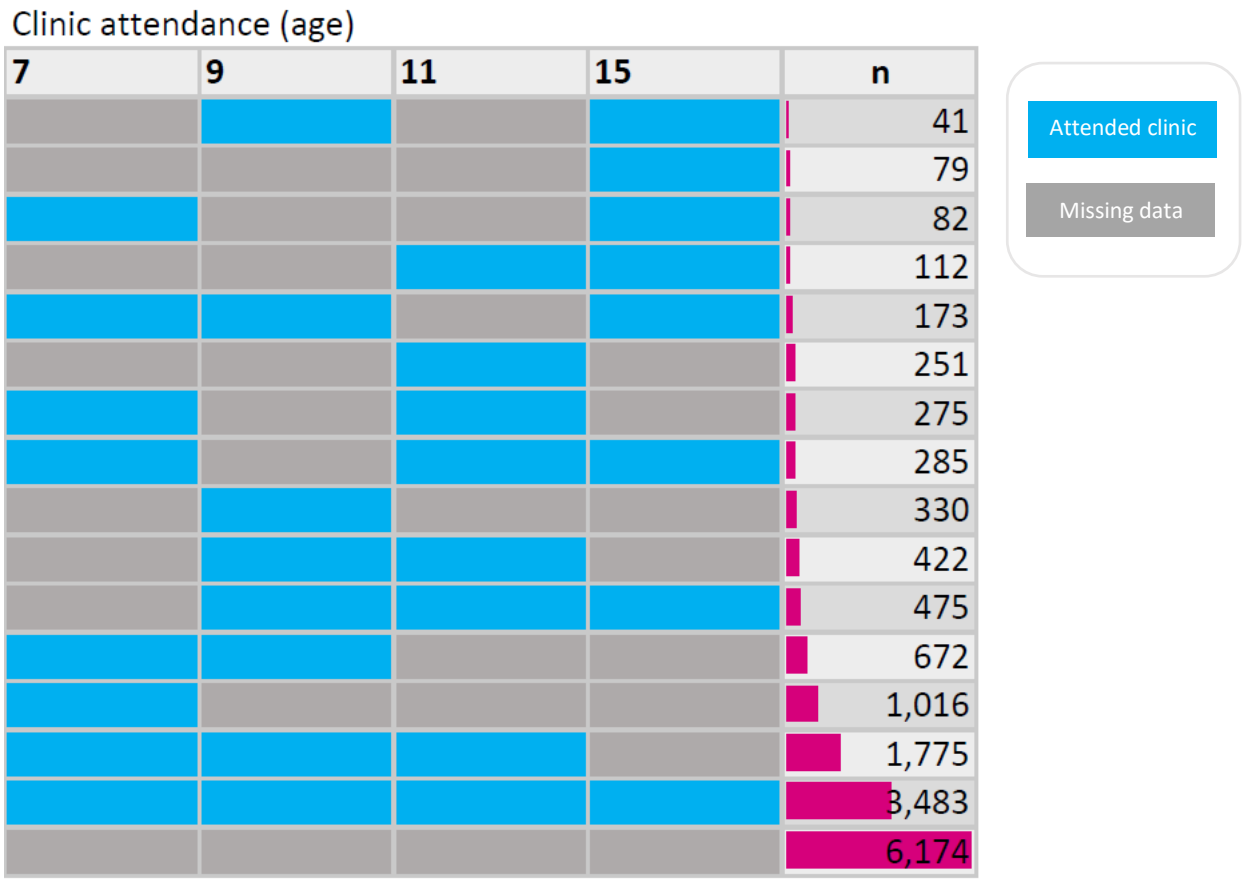


Figure 5.1 Summary of hearing assessment clinic attendance patterns in ALSPAC

Analysis of the missing data was undertaken to compare children who attended at least one clinic to children who did not attend any of the clinics against characteristics listed in Table 5.5 using chi square tests.

Table 5.5 Comparison of children with missing hearing data with children with hearing data at least at one time point in ALSPAC

Characteristic	n (%) Children who had hearing data at least at one time point	n (%) Children who did not have any hearing data	Chi square	Degree of freedom	p
Sex					
Male	4,747 (50.17)	2,951 (52.83)	9.9018	1	0.002
Female	4,714 (49.83)	2,635 (47.17)			
Ethnic group					
White	7,991 (95.75)	3,540 (93.21)	35.1212	1	<0.001
Non-white	355 (4.25)	258 (6.79)			
Socioeconomic group[a]					
I	3,750 (51.54)	1,639 (52.77)	82.7679	3	<0.001
II	1,538 (21.14)	456 (14.68)			
III	1,390 (19.10)	640 (20.61)			
V	598 (8.22)	371 (11.94)			
Social Deprivation[b]					
1	1,408 (17.59)	11 (15.94)	5.5807	9	0.781
2	1,130 (14.12)	6 (8.70)			
3	1,068 (13.34)	11 (15.94)			
4	471 (5.88)	6 (8.70)			
5	904 (11.29)	10 (14.49)			
6	555 (6.93)	2 (2.90)			
7	740 (9.24)	7 (10.14)			
8	533 (6.66)	6 (8.70)			
9	762 (9.52)	6 (8.70)			
10	434 (5.42)	4 (5.80)			
Mum's highest educational qualification					
Vocational	774 (9.11)	455 (11.41)	332.0847	3	<0.001
CSE/O levels	4,273 (50.28)	2,579 (64.65)			
A levels	2,172 (25.56)	625 (15.67)			
Degree	1,279 (15.05)	330 (8.27)			
Maternal smoking 18 weeks gest					
0	4,636 (53.76)	1,898 (41.72)	182.5873	3	<0.001
<10	1,004 (11.64)	591 (12.99)			
10-19	1,683 (19.52)	1,204 (26.47)			
>20	1,300 (15.08)	856 (18.82)			
Maternal smoking 7 years					
0	5,769 (80.72)	752 (67.50)	123.7344	3	<0.001
<10	502 (7.02)	92 (8.26)			
10-19	565 (7.91)	180 (16.16)			
>20	311 (4.35)	90 (8.08)			
Age of mother at delivery					

<16	2 (0.02)	8 (0.16)	595.7071	3	<0.001
16-25	2,095 (23.48)	2,212 (42.98)			
26-40	6,700 (75.10)	2,882 (55.99)			
>40	125 (1.40)	45 (0.87)			
Parity					
0	3,876 (45.83)	1,949 (43.55)	53.5774	3	<0.001
1-3	4,481 (52.98)	2,394 (53.50)			
4-6	97 (1.15)	127 (2.84)			
7+	4 (0.05)	5 (0.11)			

a – socioeconomic groups: I) Managerial & professional occupations II) Intermediate occupations III) Small employers & own account workers V) Semi routine & routine occupations

b – Social deprivation as indicated by Index of Multiple Deprivation deciles at age 7 with 1 representing the least deprived area and 10 indicating the most deprived area

Table 5.5 shows that a greater number of males did not attend any of the clinics. Those of a non-White background were also less likely to attend. Furthermore, children whose mothers had a lower educational qualification and who were from a lower socio-economic background were less likely to attend. Children who had parents who smoked, had younger mothers and who had a greater number of siblings were also more likely to not have attended the clinics. This analysis indicates that data are not missing at random, but that these characteristics may have influenced clinic attendance. This informs further planned analyses of the data in relation to studying long-term OM related HL.

5.5 Strengths and limitations of using the ALSPAC data

The longitudinal nature of ALSPAC and its repeated measures is a key strength in that it allows the study of long-term OM related HL, which needs to be determined based on data over time. Its prospective nature ensures that recall bias will be avoided when studying the associations between long-term OM related HL and developmental outcomes as the exposure precedes the outcome and knowledge of the outcome does not bias knowledge of the exposure. Selection bias is avoided as participants were recruited from the general population, and not selected based on participant factors which may or may not influence exposure and outcomes. It was concluded that the ALSPAC

cohort is generally representative of the UK population on a whole (Golding et al., 2001). ALSPAC has a large sample size and its collection of various measures not only means that different outcomes can be studied, but also that confounders can be controlled for in analyses.

Having said this, residual confounding may remain present as with all cohort studies. Furthermore, although generally representative of the UK population, the majority of ALSPAC participants belong to a White ethnic group and more advantaged background so may be under-representative of those from minority ethnic groups and lower social backgrounds (Boyd et al., 2013). Loss to follow up, resulting in attrition bias is a crucial limitation with longitudinal studies and for this study in particular as children are being studied at later ages so loss to follow up is more likely. This reduces the sample size as in order to determine long-term OM related HL, information obtained from attendance at hearing assessments across time is required. This could further bias the findings as it has been reported that children of more educated and older mothers were more likely to attend clinics (Northstone et al., 2005). Hence, this may need to be considered when interpreting findings in this thesis. Nevertheless, as a longitudinal population study with repeated standardised measures of hearing, analysing the data obtained by ALSPAC will provide much needed data on long-term OM related HL.

5.6 Chapter summary

This chapter has introduced the Avon Longitudinal Study of Parents and Children from which data will be analysed to address the research questions presented in Chapter 3. The hearing data available in ALSPAC has been described with a brief discussion of the strengths and limitations of using the ALSPAC data. The specific research objectives and the framework of this research will be outlined in the following chapters. The next chapter presents a descriptive analysis of the hearing data to determine the prevalence of long-term OM related HL.

Chapter 6. Long-term OM related hearing loss in ALSPAC

6.1 Introduction

As detailed in earlier chapters, there are no valid longitudinal data on OM related HL and epidemiological data on long-term OM related HL is required. Existing data on OM, either only provide cross-sectional estimates of OM/OM related HL or do not provide data on HL associated with OM and only of the presence of middle ear effusion (Midgley et al., 2000; Todberg et al., 2014; Silva et al., 1986; Bennett et al., 2001; Brennan-Jones et al., 2020; Butcher, 2020; Apostolopoulos et al., 1998; Liu et al., 2001). Furthermore, the existing longitudinal studies which have looked at OM related HL, again, either only provide data on OM related HL prevalence at one time point, do not provide age specific estimates or have used parental report measures which are not accurate measures of hearing (Bennett and Haggard, 1999; Silva et al., 1986; Bennett et al., 2001; Brennan-Jones et al., 2020). These limitations are also present with both cross-sectional and longitudinal studies of childhood HL in general from which estimates of OM related HL could be drawn from studying the prevalence of mild-moderate conductive HL (Butcher, 2020; Yiengprugsawan et al., 2013; Sheridan, 1972; Dodgeon and Shepherd, 2014; Niskar et al., 2001; Shargorodsky et al., 2010; Su and Chan, 2017; Feder et al., 2017; Hussain et al., 2011; Fitzpatrick et al., 2020).

This chapter focuses on investigating the prevalence of long-term OM related HL in ALSPAC. OM prevalence in ALSPAC has previously been studied (Midgley et al., 2000). However, while this study did not look at HL associated with OM, it also only studied the prevalence of OM in the first 5 years of life. It is known that OM is prevalent in early childhood, however data regarding the prevalence of OM beyond the age of 7 years is not as readily available. ALSPAC has repeatedly collected objective

hearing measures from the age of 7 years onwards, which will be studied and discussed in this thesis.

In this chapter, the objectives of this study and the methods used for studying the prevalence of long-term OM related HL in ALSPAC are first outlined and then the results from this analysis are presented followed by a discussion of the findings.

6.2 Study objectives

The overall aim of the first part of the research using ALSPAC data is to estimate the prevalence of long-term OM related HL between the ages of 7-15 years.

The data obtained from ALSPAC do no not allow us to distinguish between the types of OM and CHL resulting from complications of OM, therefore this research refers to the HL as OM related HL. However, it is most likely that HL would be a result of OME.

The individual research objectives are as follows:

1. To determine the mean hearing thresholds of children in ALSPAC at 7, 9, 11 & 15 years
2. To determine the prevalence of conductive hearing loss in ALSPAC at age 7, 9, 11 and 15 years.
3. To determine the prevalence of long-term (otitis media related) conductive hearing loss in ALSPAC between ages 7 and 15 years.

6.3 Methods

In order to study the prevalence of CHL in ALSPAC, the hearing thresholds for each child's ears at each frequency were averaged and categorised to give the degree of HL. Mean hearing thresholds

for each ear of each child were calculated using the five-frequency average recommended by the British Society of Audiology (British Society of Audiology, 2018) by taking the mean average of thresholds for each frequency tested. Summary descriptives of the mean hearing thresholds for the right and left ears within the whole sample with hearing data at each age were also studied.

The mean average hearing thresholds for each child were categorised to indicate whether each child had normal hearing levels or a degree of HL using the British Society of Audiology recommended audiometric descriptors (British Society of Audiology, 2018). Categories consisted of normal hearing, mild hearing loss, moderate hearing loss and severe-profound hearing loss.

6.3.1 Defining long-term OM related HL & sample selection

Although the causes of HL in ALSPAC could not be distinguished, as OM is the most common cause of CHL particularly in childhood (Bluestone, 2003; Kubba et al., 2000), the presence of CHL was taken to represent the presence of OM related HL. Long-term OM related HL in ALSPAC was defined as having mean average hearing thresholds greater than 20dBHL and bone conduction values <=25dBHL at two or more of the time points. The time points did not have to be consecutive e.g. if a child presented with hearing thresholds >20dBHL and BC thresholds <=25dBHL at ages 7 and 11 but not at age 9, they were classed as having long-term OM related HL. This meant that the sample of children to be studied had to only include children in ALSPAC who had attended two or more of the hearing assessments. Furthermore, to ensure that that the HL experienced by children was only CHL related to long-term OM, children likely to have SNHL (with average BC thresholds >25dBHL or AC thresholds >70dBHL) at any of the time points were excluded from the sample. Children with SNHL were excluded to ensure the study of long-term OM related CHL only in childhood, and not permanent HL attributed to SNHL which may also be more severe in degree as opposed to long-term OM related HL; and thus, may impact children differently.

A score pertaining to how many clinics each child attended was derived. Scores were out of four and a score of two or greater indicated that the child had attended the clinics at two or more of the four time points. These children with scores of two or greater formed the sample. Children with scores of zero or one were not part of the selected sample.

6.3.2 Assessing missing-ness

Analysis of missing-ness to compare children in the sample with the rest of the cohort was carried out to study differences between those with missing data and those without missing data in order to determine whether the data was missing at random or missing not at random. This involved running chi-square tests to determine the differences between the sample and those with missing hearing data and to observe whether these were systematic differences.

This was done to compare the selected sample to the rest of the ALSPAC cohort to determine any differences between the two proportions, which may have influenced clinic attendance.

6.3.3 Cross-sectional analysis of CHL

As OM related HL would largely present as CHL, the prevalence of CHL at each time point in this sample was studied to give an indication of how many children in this sample had OM related HL at each of the time points. This was done by looking at the average AC and average BC hearing thresholds. Average AC hearing levels greater than 20dBHL and average BC levels equal to or less than 25dBHL indicated that the child had CHL. Tympanometry values were not studied as these could differ with the OM or HL status.

Two approaches were taken where the number of children with CHL in either the better or worse ear was studied to present numbers to include children with both bilateral and unilateral CHL.

6.3.4 Determining the prevalence of long-term OM related HL

An 'OMHL' (OM related HL) score was derived for each child, which provided information on how many time points the child had OM related HL. For each time point, a score of one was assigned to indicate having CHL at that time point. If the child did not have CHL at that time point, a score of zero was assigned. Scores were out of four as there were four time points. An OMHL score of two or greater indicated that the child had long-term OM related HL.

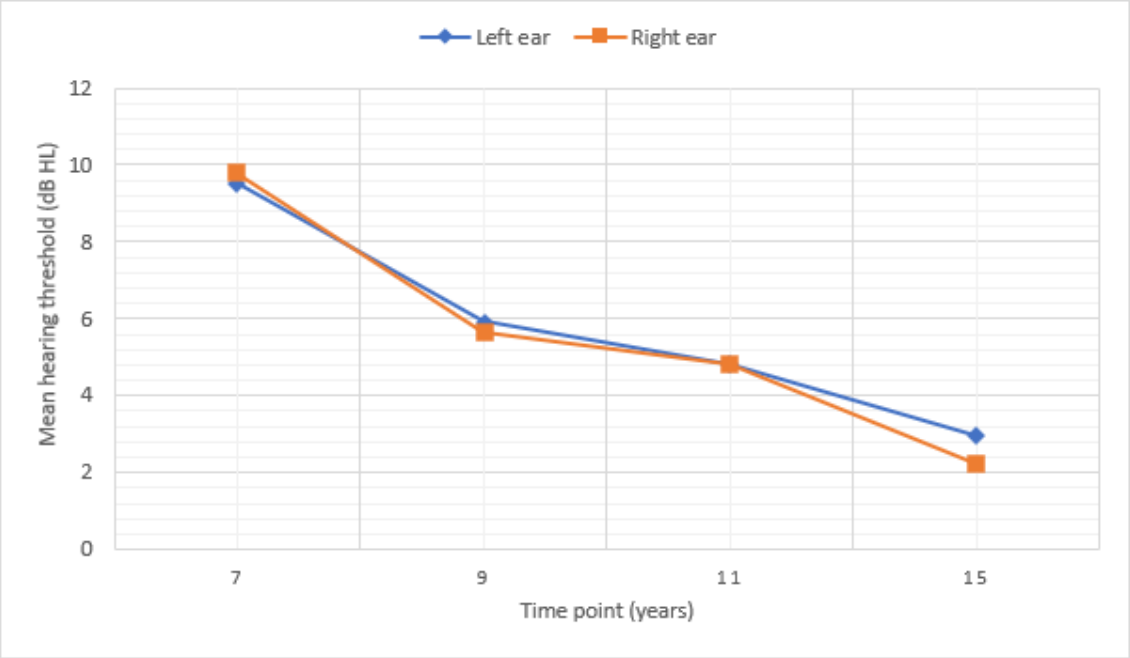
Long-term OM related HL in ALSPAC was categorised in this way due to the fluctuating nature of OM related HL. Children needed to have presented with CHL at more than one time point in order to be classified as having *long-term* OM related HL, particularly as hearing was tested at least 2 years apart. The aim of this study was to provide much needed epidemiological information of long-term OM related HL extending past later childhood through examining simply whether children presented with OM related HL at multiple time points. As OM related HL is typically mild to moderate in nature, the HL was not classified in terms of degree.

Chi-square tests were then carried out to test for differences between those with long-term OM related HL and those without long-term OM related HL.

6.4 Results

6.4.1 Average hearing thresholds

Summary descriptive statistics for the five frequency average thresholds for each ear at each time point are presented in Figure 6.1. It is important to note that the children who attended each clinic may have differed at each time point. Hence, these summaries are representative of hearing in general at each time point and do not represent trends in hearing trajectories.



		7	9	11	15
Mean					
	R	9.77	5.64	4.80	2.21
	L	9.50	5.92	4.80	2.95
Minimum					
	R	-6	-6	-10	-10
	L	-9	-7	-8	-10
Maximum					
	R	115	105	105	115
	L	111	103.75	110	105

Figure 6.1 Summary of average hearing thresholds in right ears (R) and left ears (L) of children in ALSPAC at ages 7, 9, 11 & 15 years

At all of the time points, mean hearing thresholds were within the normal range of <=20dB (British Society of Audiology, 2018). Mean thresholds for the cohort were seen to have improved in general with time with almost an 8dB decrease between ages 7 years and 15 years. Thresholds for both the right and left ears were at similar levels at all time points.

Table 6.1 displays the categorisation of hearing level and the number of children who fell into each category based on the thresholds of the right and left ear separately, as well as thresholds based on the better hearing ear. Due to the small number of children with severe and profound HL, these children were grouped together. For thresholds based on the better hearing ear, normal hearing represents children with normal hearing in at least one ear, however hearing loss represents bilateral HL.

Table 6.1 Categorisation of hearing levels for children in ALSPAC at 7, 9 11 & 15 years

Hearing status		**Time point (years) n (%)**			
		7	**9**	**11**	**15**
Normal hearing (<20dB HL)	R	7,328 (94.40)	7,166 (97.22)	6,933 (97.98)	4,655 (98.44)
	L	7,328 (94.43)	7,140 (96.89)	6,898 (97.46)	4,639 (98.08)
	Better ear	7,551 (97.27)	7,278 (98.72)	7,009 (99.03)	4,692 (99.18)
Mild hearing loss (21 – 40 dB HL)	R	385 (4.96)	171 (2.32)	112 (1.58)	60 (1.27)
	L	375 (4.83)	188 (2.55)	143 (2.02)	72 (1.52)
	Better ear	187 (2.41)	74 (1.00)	51 (0.72)	28 (0.59)
Moderate hearing loss (41 – 70 dB HL)	R	41 (0.53)	27 (0.37)	28 (0.40)	8 (0.17)
	L	49 (0.63)	35 (0.47)	28 (0.40)	14 (0.30)
	Better ear	17 (0.22)	15 (0.20)	15 (0.21)	7 (0.15)
Severe-profound hearing loss (>70 dB HL)	R	9 (0.12)	7 (0.09)	3 (0.04)	6 (0.13)
	L	8 (0.10)	6 (0.08)	4 (0.06)	5 (0.11)
	Better ear	8 (0.10)	5 (0.07)	3 (0.04)	4 (0.08)

Table 6.1 shows that at all ages most of the children tested had normal hearing levels. At age 7, around 6% of children had some degree of HL in at least one ear. Most of this HL was of a mild degree, with almost 5% being mild and only 0.5% being of a moderate degree. Furthermore, only 0.1% of children had severe-profound HL. While around 6% of children had HL in general, only just over 2% had bilateral HL at age 7. Degree of hearing was similar for the right and left ears.

At age 9, the proportion of children with normal levels of hearing increased with only 1% having bilateral HL and around 3% of children having some degree of HL in either ear. The number of children with mild and moderate HL had decreased. The greatest decrease was seen for children with mild HL, which went from ~5% at age 7 to ~3% at age 9.

At age 11, only around 2% of the cohort had HL in either ear, most of this remaining as mild HL. Less than 1% of the children now had bilateral HL.

Although fewer children attended hearing assessments at age 15, again around 2% of this sample had some degree of HL between the two ears with most of it being attributed to mild HL. Bilateral HL was still prevalent in less than 1% of children.

As can be seen at all ages, most children with HL had a mild degree of HL with only a very few children having severe to profound HL. HL prevalence decreased with time. The greatest decrease was seen with mild HL, followed by moderate HL, representing the resolution of OM related CHL.

6.4.2 Bone conduction thresholds

Bone conduction thresholds were studied for those with available BC data in order to determine how many children with HL had BC thresholds >25 dB HL at each age. Children with BC thresholds > 25dB HL would likely have SNHL, thus would need to be excluded from the sample. Table 6.2 displays the number of children with BC thresholds >25 dB HL at each age (BC testing was not carried out at age 15).

Table 6.2 Number of children in ALSPAC with BC thresholds > 25 dB HL at ages 7, 9 & 11 years

	Time point (years) n (%)		
	7	**9**	**11**
BC >25 dB HL	20 (0.26)	23 (0.31)	27 (0.38)

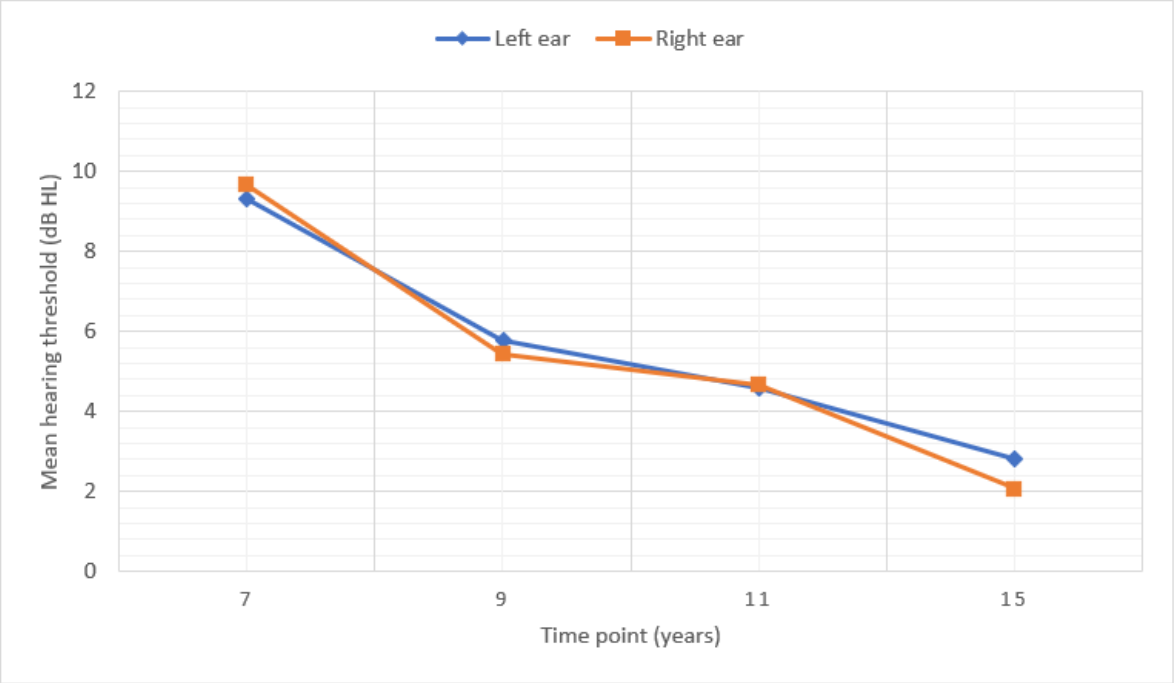
As can be seen the number of children with BC thresholds >25 dB HL was small at each age but did increase slightly with age.

6.4.3 Trend in hearing loss for children who attended all four time points

Comparisons of the hearing levels of participants are difficult to make from the data presented as the samples of children who attended the hearing assessments at each time point differ from each other. Bearing in mind that the sample sizes decreased at each time point, from the data presented for the ALSPAC cohort, the trend of improved hearing levels across time can be seen.

To study the trends in hearing trajectories the analyses were re-run for children who had hearing data at all four time points. 3,483 children from the whole ALSPAC cohort had hearing data at all time points.

Figure 6.2 shows that the mean thresholds for this group of children were slightly lower than those of the whole sample at each time point; highlighting that the hearing levels of the children who attended all the hearing assessments were overall better than the average hearing level of the whole sample.



		7	9	11	15
Mean					
	R	9.67	5.43	4.65	2.07
	L	9.31	5.76	4.58	2.81
Minimum					
	R	-6	-6	-7	-10
	L	-9	-7	-8	-10
Maximum					
	R	110	105	98.75	107.5
	L	100	103.75	98.75	90

Figure 6.2 Summary of average hearing thresholds in right ears (R) and left ears (L) of children in ALSPAC with hearing data at all four time points (ages 7, 9, 11 & 15 years)

Table 6.3 shows that the proportions of children with normal hearing and HL are similar to that of the whole cohort with 5-6% of children having some form of HL at age 7 and this reducing to ~2% at age 9 and remaining at around 1-2% at ages 11 and 15. The greatest decrease in prevalence of bilateral HL was between age 7 and 9, after which there were small decreases, which highlights the decline in prevalence of HL with later age. Table 6.4 shows that based on the better ear thresholds, the percentages of children with SNHL were similar for the whole cohort.

Table 6.3 Categorisation of hearing levels for children in ALSPAC with hearing data at all four time points (7, 9 11 & 15 years)

Hearing status		Time point (years) n (%)			
		7	9	11	15
Normal hearing (<20dB HL)	R	3,285 (94.32)	3,402 (97.67)	3,415 (98.08)	3,429 (98.48)
	L	3,296 (94.63)	3,381 (97.07)	3,400 (97.73)	3,411 (97.96)
	Better ear	3,386 (97.22)	3,444 (98.88)	3,449 (99.02)	3,453 (99.14)
Mild hearing loss (21 – 40 dB HL)	R	178 (5.11)	68 (1.97)	52 (1.49)	43 (1.23)
	L	164 (4.71)	81 (2.33)	63 (1.81)	56 (1.61)
	Better ear	86 (2.47)	30 (0.86)	24 (0.69)	22 (0.63)
Moderate hearing loss (41 – 70 dB HL)	R	17 (0.49)	9 (0.26)	13 (0.37)	6 (0.17)
	L	21 (0.60)	18 (0.52)	13 (0.37)	14 (0.40)
	Better ear	9 (0.26)	6 (0.17)	8 (0.23)	6 (0.17)
Severe-profound hearing loss (>70 dB HL)	R	3 (0.09)	4 (0.11)	2 (0.06)	4 (0.11)
	L	2 (0.06)	3 (0.09)	3 (0.09)	1 (0.03)
	Better ear	2 (0.06)	3 (0.09)	2 (0.06)	2 (0.06)

Table 6.4 Number of children in ALSPAC with hearing data at all four time points with BC thresholds > 25 dB HL at ages 7, 9 & 11 years

	Time point (years) n (%)		
	7	9	11
BC >25 dB HL	10 (0.29)	10 (0.29)	13 (0.36)

The mean thresholds for this group of children were slightly lower than those of the whole sample at each time point; highlighting that the hearing levels of the children who attended all the hearing assessments were overall better than the average hearing level of the whole sample. Nevertheless, the trends in hearing data for this group of children were similar to those for the whole cohort.

6.4.4 Sample

As mentioned in the previous chapter, 6,174 children from the 15,645 children participating in ALSPAC, did not attend any of the clinics. This meant that 9,471 children attended at least one clinic and had their hearing assessed. Of these 9,471 children, the sample for this study consisted of those

who attended two or more of the hearing assessments as indicated by the derived clinic attendance score as shown in Table 6.3.

Table 6.5 Number of clinics attended by children with hearing data from the whole ALSPAC cohort

Clinic attendance score	n (%)
1	1,676 (17.7)
2	1,604 (16.93)
3	2,708 (28.59)
4	3,483 (36.78)

Summing the frequencies of children with scores of two or greater gave a sample of 7,795 children. These children make up 82.3% of the 9,471 children who had hearing data. This sample consists of just under half of the ALSPAC cohort (49.8%). For analysis of CHL only, children who presented with BC thresholds > 25 dB HL or AC thresholds >70 dB HL at any time point were excluded from the sample as presented in Figure 6.2. This reduced the sample size to 7,737.

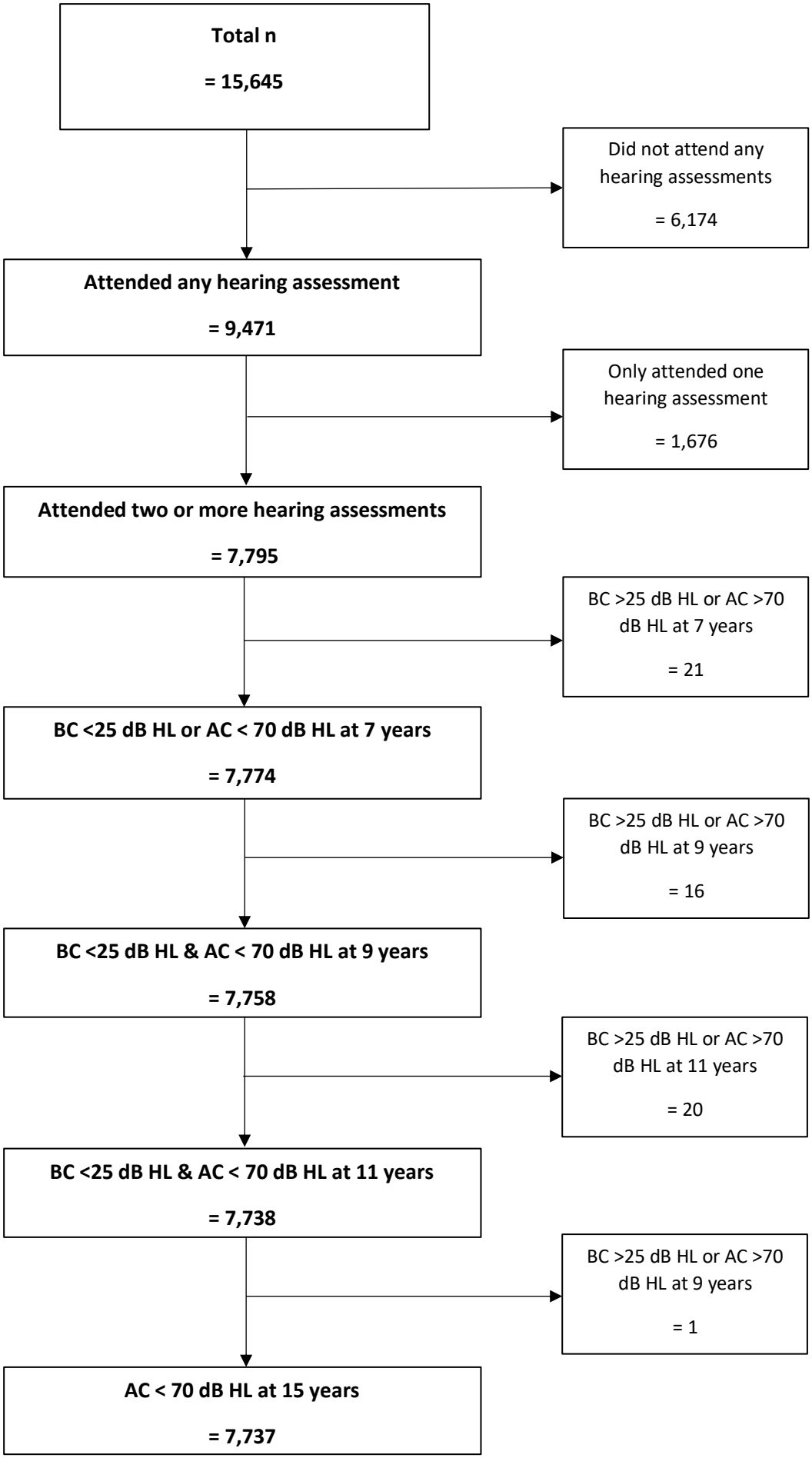


Figure 6.3 Flow chart presenting sample selection for studying prevalence of long-term OM related HL in ALSPAC

Table 6.4 shows the results of comparisons between the sample and the rest of the ALSPAC cohort. Significant differences were found for all of the characteristics with more females attending the hearing assessments compared to males, most of the sample being of a white ethnic background, belonging to a higher socio-economic group, living in the least deprived areas and having mothers who were more highly educated. Parental smoking was also lower in the sample. Fewer children of younger mothers were in the sample and parity was higher for those who were not in the sample. Differences in socioeconomic factors were found, despite the cohort representing a slightly more advantageous population.

Table 6.6 Comparison of children within the sample with the rest of the ALSPAC cohort

Characteristic	Sample n (%)	Excluded from sample n (%)	Chi square	Degree of freedom	p
Sex					
Male	3,842 (49.34)	3,856 (53.11)	21.2658	1	<0.001
Female	3,944 (50.66)	3,405 (46.89)			
Child's ethnic group					
White	6,726 (95.99)	4,805 (93.54)	37.2001	1	<0.001
Non-white	281 (4.01)	332 (6.42)			
Socioeconomic group[a]					
I	3,160 (51.39)	2,229 (52.66)	85. 6452	3	<0.001
II	1,336 (21.73)	658 (15.54)			
III	1,166 (18.96)	864 (20.41)			
V	487 (7.92)	482 (11.39)			
Social deprivation[b]					
1	1,262 (18.05)	157 (14.48)	47.1802	9	<0.001
2	1,024 (14.65)	112 (10.33)			
3	951 (13.61)	128 (11.81)			
4	409 (5.85)	68 (6.27)			
5	789 (11.29)	125 (11.53)			
6	462 (6.61)	95 (8.76)			
7	636 (9.10)	111 (10.24)			
8	462 (6.61)	77 (7.10)			
9	636 (9.10)	132 (12.18)			
10	359 (5.14)	79 (7.29)			
Mum's highest educational qualification					
Vocational	610 (8.57)	619 (11.53)	397.3948	3	<0.001

CSE/O levels	3,473 (48.78)	3,379 (62.96)			
A levels	1,901 (26.70)	896 (16.69)			
Degree	1,136 (15.96)	473 (8.81)			
Maternal smoking 18 weeks gest					
0	4,008 (55.79)	2,526 (42.18)	257.6859	3	<0.001
<10	830 (11.55)	765 (12.78)			
10-19	1,326 (18.46)	1,561 (26.07)			
>20	1,020 (14.20)	1,136 (18.97)			
Maternal smoking 7 years					
0	5,142 (82.08)	1,379 (69.09)	185.2730	3	<0.001
<10	431 (6.88)	163 (8.17)			
10-19	448 (7.15)	297 (14.88)			
>20	244 (3.89)	157 (7.87)			
Age of mother at delivery					
<16	1 (0.01)	9 (0.13)	633.9962	3	<0.001
16-25	1,580 (21.40)	2,727 (40.78)			
26-40	5,687 (77.04)	3,895 (58.25)			
>40	114 (1.54)	56 (0.84)			
Parity					
0	3,294 (46.73)	2,531 (43.01)	59.8294	3	<0.001
1-3	3,680 (52.21)	3,195 (54.30)			
4-6	71 (1.01)	153 (2.60)			
7+	4 (0.06)	5 (0.08)			

a – socioeconomic groups: I) Managerial & professional occupations II) Intermediate occupations III) Small employers & own account workers V) Semi routine & routine occupations

b – Social deprivation as indicated by Index of Multiple Deprivation deciles at age 7 with 1 representing the least deprived area and 10 indicating the most deprived area

6.4.5 Missing-ness of hearing data

Clinic attendance patterns for this sample are presented in Figure 6.3. Less than half the children in this sample (44.7%) attended at all four time points. Children were more likely to have attended the earlier clinics and more likely to have attended clinics at consecutive time points as opposed to random time points. For children who attended at two time points, attending an earlier time point and a later time point was less common (e.g. 7 & 15, 9 & 15). Attendance at later clinics and not earlier ones on a whole was also less common.

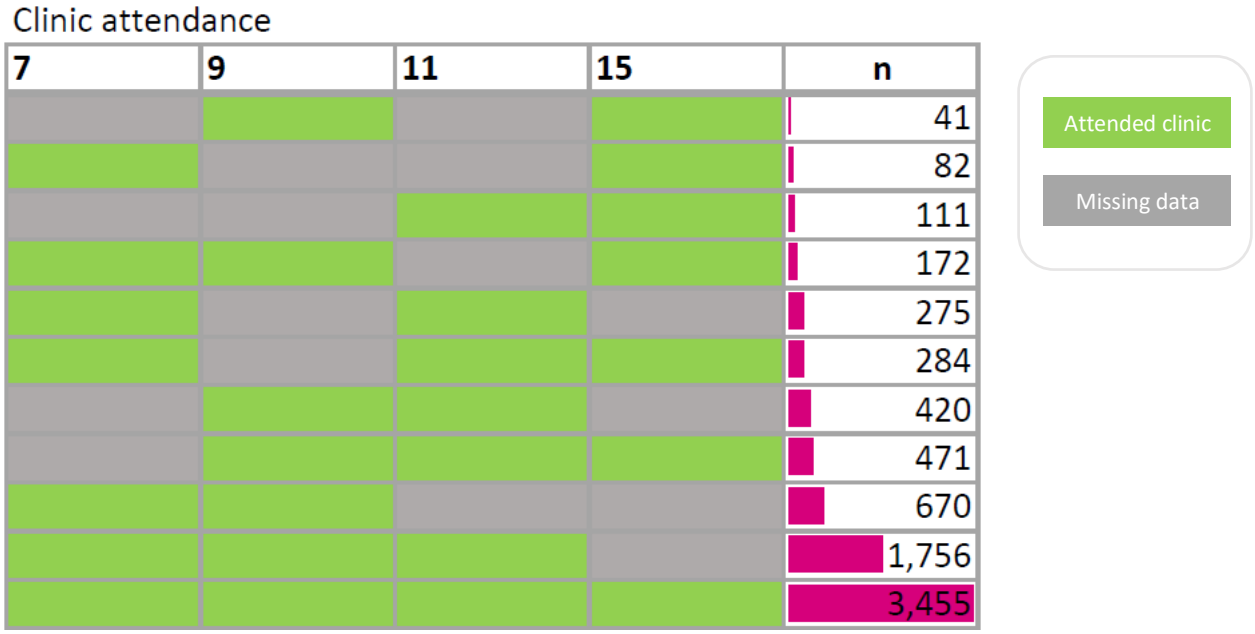


Figure 6.4 Summary of hearing assessment clinic attendance patterns in ALSPAC by children in the sample

6.4.6 Cross-sectional analysis of CHL

An initial look at the data consisted of cross-sectional analyses of CHL in ALSPAC at each age in children who attended 2 or more clinics, as these numbers would be used to determine who had long-term OM related HL either unilaterally or bilaterally.

Table 6.7 Number of children in the sample with conductive hearing loss (CHL) at each time point

	Age (years)			
	7	**9**	**11**	**15**
Number of children with CHL (based on worse ear) (%)	515 (6.61%)	285 (3.66)	205 (2.63)	107 (1.37)
Number of children with CHL (based on better ear) (%)	152 (1.95)	57 (0.73)	37 (0.47)	25 (0.32)

It can be seen in Table 6.5 that the percentage of children with both unilateral and bilateral CHL decreases with age. The number of children with CHL at age 9 almost decreased by half from age 7, after which the decreases were a lot smaller.

6.4.7 Prevalence of long-term OM related HL

Using the data on CHL at each time point, the prevalence of long-term OM related HL was estimated. Figure 6.4 shows the number of children in the sample with CHL at either one, two, three or all four of the time points. The numbers of children with CHL at two or more time points were then combined to give a total of 210 based on hearing thresholds in the worse ear and 32 based on hearing thresholds in the better ear. These are the numbers of children with long-term OM related HL in the sample.

Examining the hearing levels based on the worse ear gives us cases of both unilateral and bilateral long-term CHL, which gives an estimate of 2.69% of the sample having long-term OM related HL with 0.41% of the sample having bilateral long-term OM related HL.

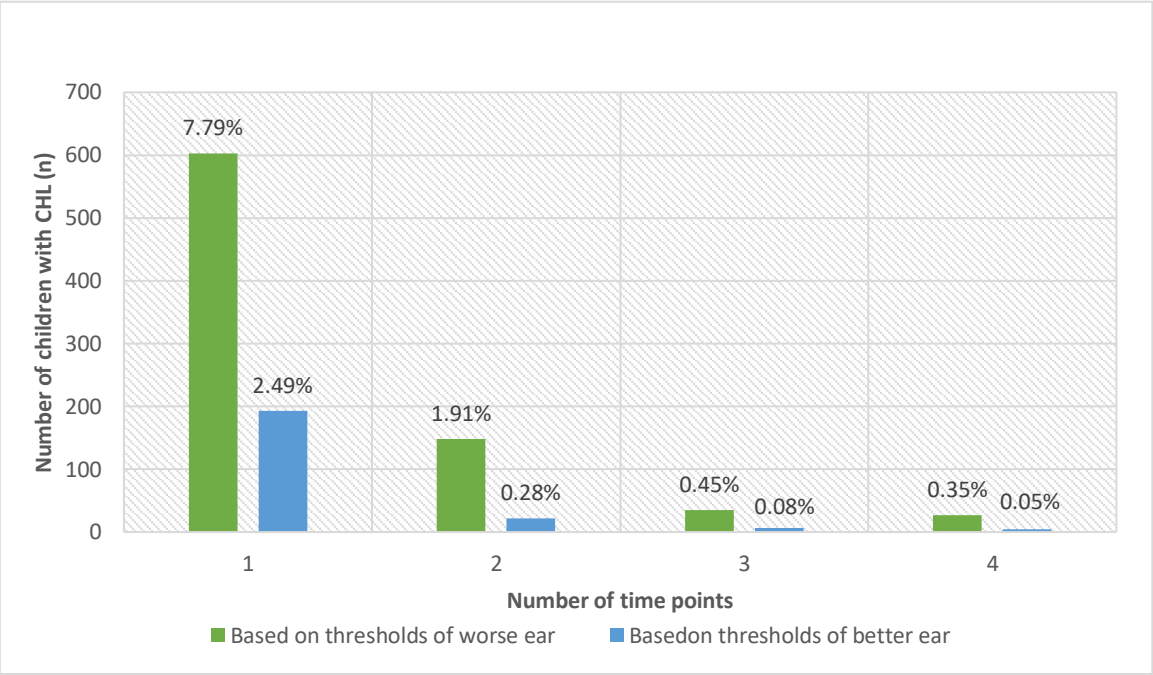


Figure 6.5 n (%) for children in the sample with conductive hearing loss at 1, 2, 3 or 4 time points

Chi-square tests were then performed to compare children with and without long-term OM related HL in the sample to observe what factors may have been linked to developing long-term OM related HL. The analysis showed that children in the sample with long-term OM related HL were less likely to come from families with more than 3 siblings. There were no other differences in other characteristics.

6.4.8 Patterns of hearing loss

For the 210 children with long-term OM related HL, the time points at which they had HL based on the available data were examined and are presented in Figure 6.5.

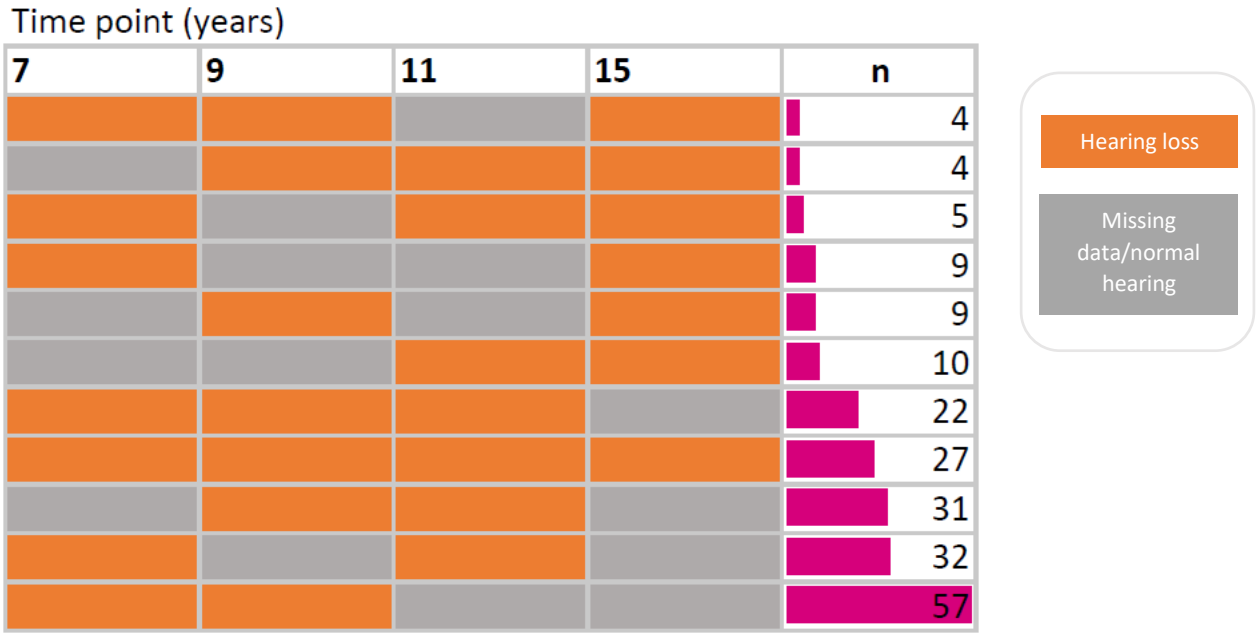


Figure 6.6 Summary of hearing loss trajectories for children with long-term OM related HL in ALSPAC

Most of these children experienced long-term OM related HL at ages 7 and 9 after which they presented with normal hearing levels or didn't attend the clinics. However, these children only made up just over a quarter of the group. Most of the children with long-term OM related HL had HL at ages 9 and 11. Only 27 (0.48%) of these children experienced HL across all 4 time points. HL was mostly experienced across two time points both consecutively and non-consecutively, representing persistent and recurrent HL. HL at the earlier ages of 7 and 9 was only seen to resolve at later ages for a few children with most of the HL recurring at later ages.

6.5 Discussion

6.5.1 Hearing loss prevalence

HL prevalence in later childhood and early adolescence in the ALSPAC cohort has been estimated. ALSPAC is the only longitudinal population study to have obtained repeated standardised hearing measures from a large number of children. Other large longitudinal studies on childhood HL (Butcher, 2020; Bennett and Haggard, 1999; Yiengprugsawan et al., 2013) have utilised parental report of HL which may lack accuracy, particularly for HL associated with OM (Rosenfeld et al., 1998), Thus, the analysis of this data adds valuable information to what is known about childhood HL.

At age 7, just under 6% of children were found to have HL in either the right or left ear and 2.7% of children had bilateral HL. HL prevalence decreased as children aged. At age 9, the prevalence of HL in either the right or left ear almost halved to around 3%. This was also the case for the proportion of children with bilateral HL at age 9, which reduced to 1.3%. At age 11, the percentage of children with HL further decreased, with around 2% of children having HL in either the right or left ear and 0.97% having bilateral HL. At age 15, just under 2% of children had HL in either ear and only 0.82% had bilateral HL. These findings show that the prevalence of HL declined with age with the rate of decline decreasing at each time point.

Other epidemiological studies, despite differing in the HL threshold cut-offs used, have reported similar rates of HL. However, rather than reporting prevalence rates at individual ages, these studies have studied prevalence of HL in groups of children of different ages or within a specific age range. For example, from their review of epidemiological studies on hearing impairment in the US in new-borns, children & adolescents <20 years of age, Mehra et al. (2009) reported a prevalence of 3.1% for any HL (unilateral/bilateral >25dB) and 0.9% for bilateral HL >25dB. While they used a slightly higher cut-off of 25dB and included new-borns, children and adolescents in their review, the rates they have reported are similar to the rates estimated in ALSPAC, in particular to those at the later ages. A study on the national prevalence of HL in Canadian children and adolescents aged 6-19 years reported a prevalence of 7.7% for HL measured by audiometry (Feder et al., 2017). However, when based on the four-frequency average similar to the five-frequency average used in this study, the

prevalence reduced to 4.7%. This study covers a greater age range, hence it would be expected for the prevalence of HL to be higher in this sample.

Prevalence rates of HL in the US have also been cross-sectionally determined for 6-19-year olds during the years 1988-1994, 2005-2006, 2007-2008 & 2009-2010 via the US National Health and Nutrition Examination Survey (NHANES). Prevalence of any HL >15dB for 6-19 year olds during 1988-1994 was 14.9% (Niskar et al., 1998), for 12-19 year olds during 2005-2006 was 19.5% (Shargorodsky et al., 2010), for 12-19 year olds during 2007-2008 was 22.5% and for 12-19 year olds during 2009-2010 was 15.2% (Su and Chan, 2017). These prevalence rates are much higher than those found in ALSPAC, however the age range considered is greater and hearing threshold cut-off was lower than used with the ALSPAC data, hence, more children would be classified as having HL.

The findings from within ALSPAC demonstrate that HL prevalence decreases with age which is also in line with reports from other studies which report higher HL prevalence rates for children of younger ages. A study on 4-9 year old Canadian children by Fitzpatrick et al. (2020) found that 19.3% of the children had HL. 11.3% had unilateral HL, while 7.5% had bilateral HL. In this study the HL threshold cut-off was 30dB and yet, the prevalence was higher than those found in ALSPAC in this younger group of children. Furthermore, 7% of 10-year-old children in the 1970s British Birth Cohort (BC70) were found to have bilateral HL (Dodgeon and Shepherd, 2014). In a study of Greenlandic school children aged 4-10 years, the prevalence of HL was reported to be 6.5% (Avnstorp et al., 2016). Where studies have included children within a greater age range and thus older children, HL prevalence reports are lower, between 5-6% (Apostolopoulos et al., 1998; Ayukawa et al., 2004) More so, a review by Wang et al. (2019) on studies of children of any age up to 18 years reported a prevalence of 8.1% for bilateral HL >20dB. This greater prevalence for bilateral HL may be representative of the greater age range and inclusion of younger children. However, this reduced to 2.2% when the cut off was 25dB.

Higher prevalence rates, however, have been reported for populations from developing countries. Oyewumi and Adejumo (2011) reported a prevalence rate of 5.99% for bilateral HL in 300 Nigerian school children aged up to 14 years. Hussain et al. (2011) studied 5,120 school children aged between 5-15 years from Pakistan and found that 13.6% had some degree of HL. In addition, prevalence of HL for school children aged 6-19 years in Peru was found to be 6.9% (Czechowicz et al., 2010). This higher prevalence in developing countries is likely characteristic of the differences in socioeconomic characteristics between these samples and the ALSPAC cohort.

Estimating the prevalence of HL in general at 7, 9, 11 and 15 years in ALSPAC was required in order to accurately estimate the prevalence of long-term OM related HL. This allowed comparison of childhood HL with figures presented in another UK longitudinal study, the Millennium Cohort Study (MCS). Prevalence of childhood HL in the MCS at age 7 was found to be 6.3%, at age 11 was 4.7% and at 14 years was 3.9%. These rates are higher than those found in ALSPAC, nonetheless, the MCS HL data was parent reported, thus may not represent the actual hearing levels of the cohort as the hearing measure was subjective. Having said this, analysis of overall HL in ALSPAC showed that around 5.6% of children had HL at 7 years. HL prevalence at age 7 in the MCS was not much higher and was reported as 6.3%. This indicates that around 6% of children in the UK experience HL at age 7.

Nevertheless, although HL prevalence rates in both ALSPAC and the MCS were found to reduce with age, 1.9% of children experienced any HL at age 15 in ALSPAC and in the MCS it was reported that 3.9% of children experienced HL at age 14. This is twice the proportion of children in ALSPAC with HL at a similar age and may represent the bias in the self-reported measure of HL at age 14 in the MCS. Though, having said this the sample of children with hearing data at age 14 in the MCS was considerably larger than the sample of children with hearing data at age 15 in ALSPAC.

6.5.2 Degree of HL

At all of the time points, the majority of hearing losses were of a mild degree in ALSPAC. At age 7, 88.2% of children with HL had mild HL, at age 9, 78.7% had a mild degree of HL, at age 11, 73.9% had HL of a mild degree and at age 15, 71.8% had a mild degree of HL. While 8% of children had a moderate degree of HL at age 7, at the later ages 15-20% of children had a moderate degree of HL. At all ages, only a few children had severe-profound HL. These findings are suggestive of HL at age 7 mainly being associated with early OM and thus of a mild degree. However, at age 9 and above, more children presented with HL of a moderate degree, which is indicative of children possibly experiencing OM over a longer period, or complications of OM.

Findings from other epidemiological studies on childhood HL, also support these findings in ALSPAC. The NHANES studies found that most of the HL experienced by 6-19-year-old children was mild-moderate in degree, as opposed to severe-profound. These rates are also similar to those for developing countries (Oyewumi and Adejumo, 2011; Hussain et al., 2011). Findings from the BC70 study showed that 59.1% of children with bilateral HL had bilateral mild HL, whereas only 6.02% & 1.43% had bilateral moderate and bilateral severe HL, respectively. Feder et al. (2017) report that mild HL was more common than moderate or worse HL in their study of 6-19-year-old Canadian children and adolescents. The prevalence rate of 3.1% for bilateral HL in US children reported by Mehra et al. (2009) was reduced to 0.3% when considering moderate or worse HL. Furthermore, the pooled prevalence rate reported by Wang et al. (2019) reduced from 8.1% for HL >20dB to 0.9% for HL >40dB. These findings from other epidemiological studies demonstrate further that most childhood HL is of a mild degree.

6.5.3 Conductive HL

With BC thresholds for the whole cohort showing that only 20-27 children had BC thresholds > 25 dB HL at ages 7 to 11 years, HL in ALSPAC was seen to largely be of a conductive nature. Furthermore, with HL prevalence generally decreasing with age, this indicates that most of the HL experienced by children was likely to be conductive as opposed to permanent SNHL. Although there is variability in prevalence rates of HL in other studies, studies have also reported that most hearing losses were conductive. 57.7% of HL in Chinese children was conductive (Liu et al., 2001); 88.2% of Pakistani school children had conductive HL (Hussain et al., 2011) and 69.6% of HL in children from Peru was conductive (Czechowicz et al., 2010).

Within the sample of ALSPAC studied for long-term OM related HL, the proportion of children with CHL decreased at each time point which may be indicative of temporary HL attributed to OM. Although we cannot be certain that the CHL experienced by children is solely related to OM, it is most likely. Supporting evidence is presented by Brennan-Jones et al. (2020) who reported a prevalence of bilateral HL >25dB associated with OM in 5 to 7 year olds in the Western Australian Pregnancy Cohort Study (WAPCS) of 2.1%. Bilateral HL not limited to CHL at age 7 in ALSPAC was found to be present in 2.3% of children. BC thresholds in ALSPAC at age 7 were greater than 25 dB HL in 0.26%, indicating SNHL in these children, thereby indicating that the prevalence of bilateral CHL in ALSPAC at age 7 was similar to the prevalence of bilateral OM related HL in the WAPCS in 5 to 7-year olds.

In addition, the prevalence of OM in ALSPAC between the ages of 8 months and 5 years was documented by Midgley et al. (2000). They reported that the prevalence of OM at 8 months was between 16.4 - 36.6% and at age 5 ranged between 3.1-16%. Although classification of OM in ALSPAC in this earlier study was based on otoscopy and tympanometry with hearing levels not being assessed, the findings show that OM prevalence decreased as children got older. The analyses of HL in ALSPAC at ages 7-15 presented in this chapter further show that the prevalence of OM related HL decreased with increasing age.

6.5.4 Long-term OM related HL

Most hearing loss in ALSPAC was of a mild-moderate degree and was conductive in nature, which is evident of OM related HL. The prevalence of long-term OM related HL in ALSPAC was estimated to be 2.69%. While there are epidemiological studies that have looked at prevalence of OM and HL in childhood, no known population studies have studied the prevalence of long-term OM related HL as done in this thesis. As ALSPAC took repeated measures of hearing during later childhood and early adolescence, the proportion of children with long-term OM related HL was estimated which provides us with important new information in regard to OM in childhood. This study has shown that although small, there is a group of children for whom OM fluctuates and does not completely resolve, whether that is spontaneously or with treatment, and results in children experiencing HL into adolescence. The hearing loss trajectories of this group of children demonstrate the inconsistent nature of this long-term CHL experienced overtime and into adolescence. Albeit the expected short-lived nature of OM in childhood, the importance of investigating the impact of this long-term HL on child development is highlighted as these children may require additional support to that provided for children with the more commonly experienced temporary OM and HL.

Furthermore, a study looking at 11-24 year olds with a childhood history of CSOM by Jensen et al. (2013) supports this conclusion. CSOM may develop from an initial history of OM, thus the participants in Jensen et al.'s study likely would have had long-term OM related HL. Their findings show that 2-3% still had HL in adolescence and early adulthood, which is of concern, considering that most families of children with OM in childhood are told that the condition is temporary and should resolve. In fact, some of the cohort still presented with OME and some had scarring on their eardrums. When these children were considered, OM accounted for over 75% of all hearing losses of

11-15-year olds in this cohort. These findings from Jensen et al. highlight the extent to which OM may lead to long-term HL.

Other epidemiological studies have also reported estimated prevalence rates of around 2% for OM and childhood HL in general (Brennan-Jones et al., 2020; Butcher, 2020). In ALSPAC, this 2.69% represents both unilateral and bilateral OM related HL and is comparable to the prevalence of OM related HL reported by Brennan-Jones et al. (2020) in the WAPCS. Although slightly lower, Brennan-Jones et al. (2020) found this prevalence to be for one time point and for bilateral HL as opposed to both bilateral and unilateral HL. Furthermore, the threshold cut-off for HL used by Brennan-Jones et al. (2020) was 26 dB HL, while in this thesis the cut-off was lower at 20 dB HL. Having said this, bilateral CHL in ALSPAC at age 7 was estimated to be 2.3%, thus is similar to the prevalence reported by Brennan-Jones et al. (2020) in the WAPCS.

Furthermore, the prevalence rate for long-term OM reported HL found in ALSPAC seems fitting when comparing to the general estimates of childhood HL in the MCS. In the MCS, while prevalence of HL in infancy only and other early onset HL with resolution was found to be experienced by almost 16% of children, early onset HL without resolution, late onset HL with resolution, and late onset HL without resolution which would be representative of the long-term OM related HL experienced by children in ALSPAC to some extent, was found to be prevalent in around 2% of children (Butcher, 2020).

Given that a small number of children go on to have long-term OM related HL, it is important to identify factors that may predispose children to developing long-term OM related HL. Children with and without long-term OM related HL in ALSPAC were compared to identify any potential risk factors. Children with long-term OM related HL were less likely to come from families with a greater number of siblings. However, analyses comparing the sample to the rest of the cohort showed that children with fewer number of siblings were more likely to attend clinics, hence, this difference in relation to parity may be brought about by the definition of the long-term OM related HL exposure

in this study of presenting with CHL at two or more of the time points which requires children to have attended the hearing assessment clinics.

Differences between children with and without long-term OM related HL in other characteristics were not found. Though, as mentioned previously, not only was the ALSPAC sample more advantaged than the general UK population, but there were significant differences between children who actually attended the hearing assessments and children who did not attend. Therefore, the sample was biased in that the ALSPAC participants were more socially advantaged than the general population. This has important implications for our findings, as many identified risk factors for OM are socioeconomically related, with children from lower social backgrounds being more likely to develop OM. Therefore, the estimates of OM related HL in ALSPAC may underestimate the prevalence of OM related HL, and particularly long-term OM related HL. Nonetheless, given these findings and that the proportion of children with long-term OM related HL in the general population may be greater than 2.7%, it is of importance that the impact of this long-term HL on children and adolescents is investigated in order to identify areas of support that are potentially needed for children when they are diagnosed with OM.

6.6 Chapter summary

This chapter has presented a descriptive analysis of the hearing data available in ALSPAC at ages 7, 9, 11 & 15 years to study the prevalence of HL in the ALSPAC cohort. The prevalence of HL was estimated at each age and detailed in terms of degree and likely type of HL. Most HL was conductive and of a mild-moderate degree. Prevalence of HL decreased with age, but few children still presented with mild-moderate CHL at age 15. The prevalence of long-term OM related HL between the ages of 7-15 years was estimated as 2.69%, informing us that over 2% of children experience on going mild-moderate CHL in later childhood and adolescence. The next stage of analysis involves

investigating how this long-term HL may potentially influence development which is detailed in the next chapter.

Chapter 7. Long-term OM and related HL and its impact on developmental outcomes in ALSPAC

7.1 Introduction

As discussed in chapter 2, there is inconsistent evidence of the impact of OM related HL on development. A systematic review of the literature on long-term OM related HL and its impact on cognition and academic ability was presented in chapter 4. However, the evidence was weak and as well as there being inconsistency in the outcome measures used, the literature presents a lack of large studies focusing on OM related HL measured using standardised measures of hearing at multiple time points, therefore, further evidence from longitudinal studies is needed.

The previous chapter revealed that just under 3% of children in ALSPAC experienced long-term OM related HL between the ages of 7 and 15 years. This chapter describes the analysis of the ALSPAC data to determine the impact of this long-term OM related HL on mental health and cognitive and educational outcomes. The study objectives are first presented followed by the conceptual framework for this work. The reader is then presented with a discussion pertaining to the selection of outcomes in ALSPAC to be studied. The methods of analysis are outlined and finally the results of the analyses are presented, with the chapter concluding with a discussion of the findings.

7.2 Research objectives

1. To examine the association between long-term (otitis media related) conductive hearing loss and Key Stage 2 SATs at age 10/11 years in the ALSPAC cohort.
2. To examine the association between long-term (otitis media related) conductive hearing loss and GCSE grades at 15/16 years in the ALSPAC cohort.
3. To examine the association between long-term (otitis media related) conductive hearing loss and IQ at age 15 in the ALSPAC cohort.
4. To examine the association between long-term (otitis media related) conductive hearing loss and mental health at ages 10 & 15 in the ALSPAC cohort.

7.3 Conceptual framework for analysis of associations

The rationale for studying the impact of long-term OM related HL on cognitive and educational outcomes and mental health was discussed in chapters 2 and 3. In this section, the hypothesised relationships between long-term OM related HL and these outcomes, while considering potential confounding factors are presented. Confounders are defined as 'factors that explain or produce all or part of the difference between the measure of association and the measure of effect that would be obtained with a counterfactual ideal' (Greenland et al., 2008). They are variables which are related to both the exposure and outcome variables and so confound the association between exposure and outcome (Bhopal, 2016). Not accounting for these factors leads to error in data interpretation.

Figures 7.1 & 7.2 display summaries of the hypothesised relationships between long-term OM related HL and education and mental health, including potential confounding variables through a directed acyclic graph (DAG). A DAG is essentially a causal diagram that makes explicit the postulated relations between variables and informs analysis (Bhopal, 2016). The DAGs are based on the variables available in ALSPAC as analyses can only be conducted with the available relevant data.

Covariates are factors that may also be related to the outcome variable, but not exposure variable (Salkind, 2010). Factors that may explain how a relationship between the exposure and outcome arises are known as mediators (Corraini et al., 2017). However, these factors are not displayed and discussed and associations accounting for these variables will not be analysed as this is outside of the scope for this thesis. Although the DAGs represent IQ as being on the causal pathway as a mediator, IQ will be investigated as part of the pathway for associations with educational achievement and mental health, but as an outcome and not through mediation analysis.

A more detailed discussion of the selected confounders is presented following the DAGs.

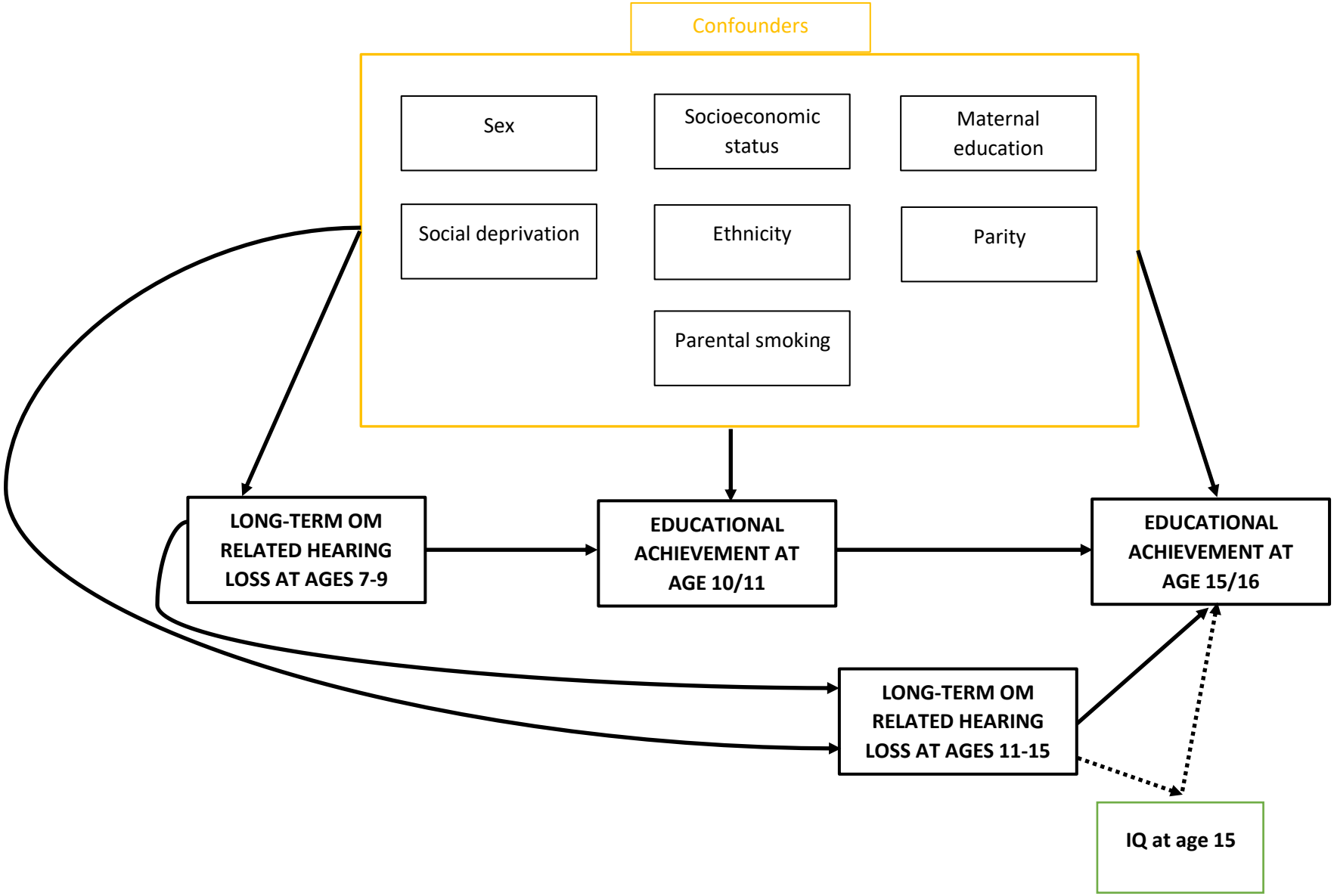


Figure 7.1 Hypothesised relationships between long-term OM related hearing loss and educational achievement

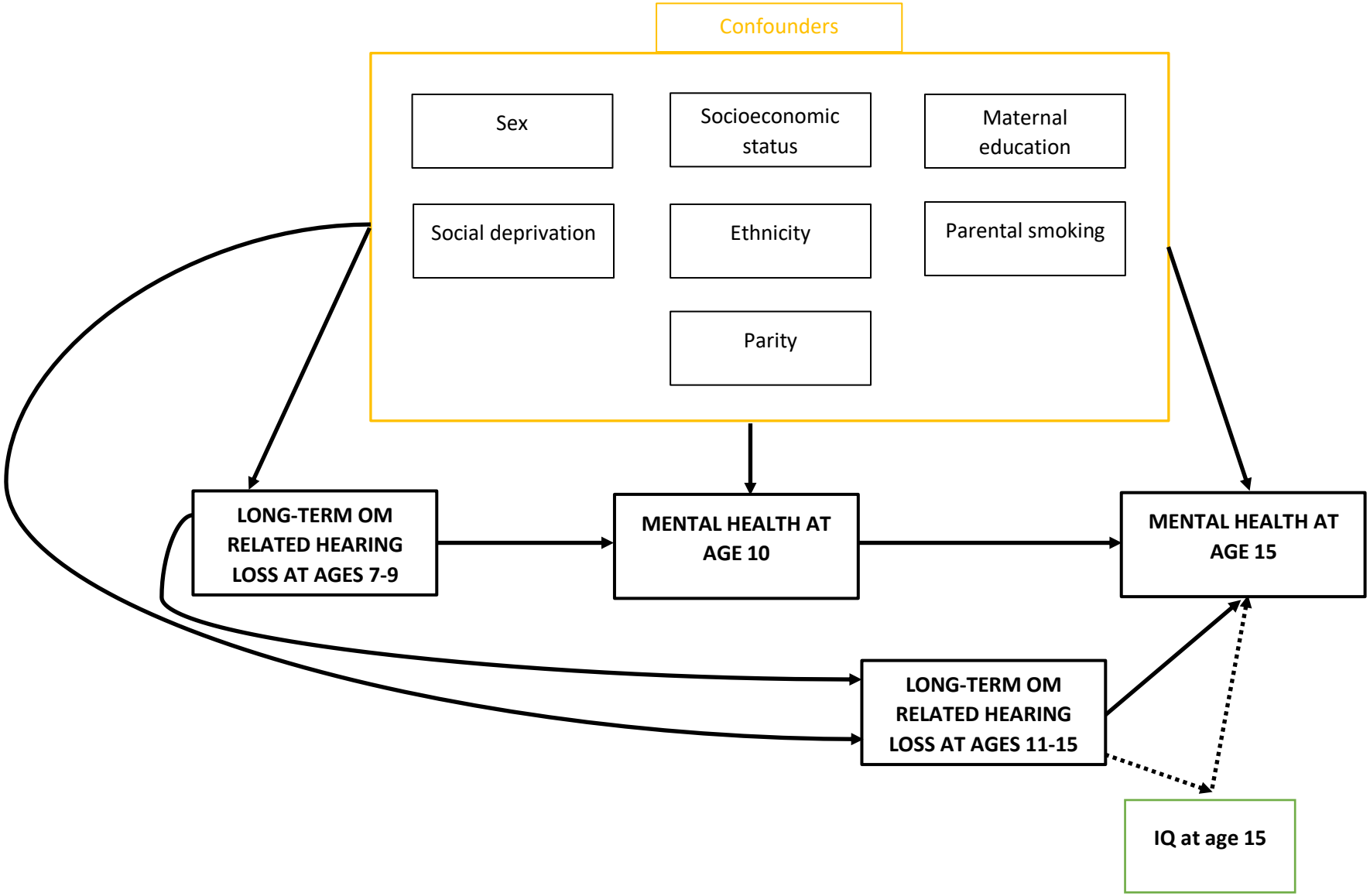


Figure 7.2 Hypothesised relationships between long-term OM related hearing loss and mental health

7.3.1 Confounders

As mentioned, confounders are variables which relate to both the exposure and outcome variables but are not on the causal pathway. Potential confounding factors in relation to long-term OM related HL and educational achievement and mental health include sex, maternal education, socioeconomic status, social deprivation, large family size, ethnicity and parental smoking and congenital defects relating to craniofacial abnormalities. Evidence supporting the use of these factors as confounders is given below.

Sex differences in OM have been found to be present as OM has been reported as being more common amongst males, with males being more prone to experiencing persistent OM (Caceres Udina Ma et al., 2004; Apostolopoulos et al., 1998; Stewart I, 1984; Birch and Elbrond, 1986). Differences in the educational attainment of males and females have also long been reported, with females on average performing better than males (DfES, 2007; Gibb et al., 2008). Furthermore, while there is no consistent evidence for sex differences in mental health with more research required, depression and anxiety are more commonly diagnosed in women (WHO, 2021). Therefore, sex differences are likely to be present with the prevalence of long-term OM related HL and its influence on outcomes and should be adjusted for.

Differences in rates of OM between different ethnic groups have been reported. OM has been found to be more commonly acquired by Inuits from Alaska and Canada, American Indian children (Apache) and Australian aborigines (Baraibar, 1997). Caucasian children are reported to have an intermediate frequency of OM, while Afro-American black children are reported to have lower rates of OM (Baraibar, 1997; Casselbrant and Mandel, 2003). However, it is not clear whether these differences are due to ethnicity being the risk factor itself or whether this is due to different ethnic groups having varying levels of access to medical care. In terms of educational attainment, children from ethnic minority groups have been seen to perform better than White children from similar

socioeconomic backgrounds. But it is thought that this may be explained by the differences in parental and student factors such as aspirations and expectations with White children having younger parents with views placing less importance on education (Stokes et al., 2015). Moreover, black and minority ethnic (BAME) groups tend to belong to lower social backgrounds which may in turn result in poorer educational outcomes and high rates of unemployment. Furthermore, poorer educational outcomes and unemployment are risk factors to mental health (Memon et al., 2016). Additionally, individuals from BAME are more likely to experience racism and discrimination and research suggests that this exposure can lead to issues such as psychosis and depression (Gibbons et al., 2012; Williams, 2018; Williams and Williams-Morris, 2000; Wallace et al., 2016).

Differences in educational achievement and mental health issues between ethnic groups may in part be explained by socioeconomic factors as BAME groups tend to belong to lower social backgrounds (Banerjee, 2016; Memon et al., 2016). OM has also been reported as being more common in children who are from a lower socioeconomic background compared to children from higher backgrounds (Casselbrant and Mandel, 2003 ; Baraibar, 1997; Caceres Udina Ma et al., 2004; Abou-Halawa and Alhumaid, 2014; Nieman et al., 2016; Adeyemo, 2012; Almudhaibery et al., 2019). This may be representative of the fact that those from lower socioeconomic backgrounds do not have the same access to services as those from higher backgrounds. This can involve living in areas that are more socially deprived, which is a known determinant of health (Chivu and Reidpath, 2010). More so, children whose mothers had a lower level of education were more likely to have OM than those with mothers with a higher level of education (Apostolopoulos et al., 1998). Level of education could be viewed as a marker of socioeconomic position, nonetheless, differences in paternal education were not reported as significant. Maternal education on its own may indicate mother's knowledge of risk factors and about the condition in general, where poor knowledge itself may be a risk factor for OM in young children. A study found that parents from a lower socioeconomic background had a poorer knowledge of risk factors for OM and that presence of risk factors was higher amongst those with lower socioeconomic status (Adeyemo, 2012). Hence, socioeconomic

position may be a marker for all these other risk factors. Similarly, children with parents who are more highly educated tend to achieve better than those with parents who are not as educated. Being more highly educated puts these parents at an advantage to support and provide for their children, this including providing a better educational environment (Dickson et al., 2016). While poorer educational outcomes put individuals at risk for mental health issues, socioeconomic determinants including maternal education and deprivation have also been found to be related to child mental health with children from lower socioeconomic backgrounds and with mothers who are less educated being more likely to exhibit mental health issues (Sonego et al., 2013; Arroyo-Borrell et al., 2017; NHS Digital, 2018). This may be as it is more likely that children of individuals with lower levels of education also receive lower levels of education and so are more likely to experience mental health issues. But also as parental SES factors may influence their emotional well-being and therefore their parenting practices which affect the child (Bøe et al., 2014).

Number of siblings/large family size has been found to be a risk factor for OM in some studies, particularly for recurrent and chronic OM (Abou-Halawa and Alhumaid, 2014; Adeyemo, 2012; Fliss et al., 1991). An increasing number of siblings has also been negatively linked to educational outcomes with later born children achieving lower than their older siblings (Feng, 2020; Black et al., 2005). Family factors including, large family size and overcrowding in the home have also been found to be associated with poor mental health in children and adolescents which is linked to the availability of family and social resources (Wille et al., 2008).

Children with parents who smoke may be more prone to negative effects. Passive smoking has been found to increase the risk of chronic OM as it is linked to increased respiratory issues (Kraemer et al., 1983; Apostolopoulos et al., 1998; Güler et al., 2018). Prenatal tobacco exposure has also been found to potentially lead to cognitive and academic deficits, learning disabilities, impulsivity, auditory processing deficits, and decreased performance on intelligence tests in childhood. Furthermore, environmental tobacco exposure has been found to be associated with failure on

academic assessments as well as symptoms of depression and anxiety (Collins et al., 2007; Bandiera et al., 2011). Therefore, parental smoking may be linked to occurrence of OM and poorer educational achievement and mental health issues.

7.4 Methods

7.4.1 Selection of measures

ALSPAC has collected data on a range of areas pertinent to health and development with there being many measures that have been carried out at different ages which may be of relevance to this study. The ALSPAC data dictionary and variable log were browsed in order to select appropriate measures taken at the appropriate time points.

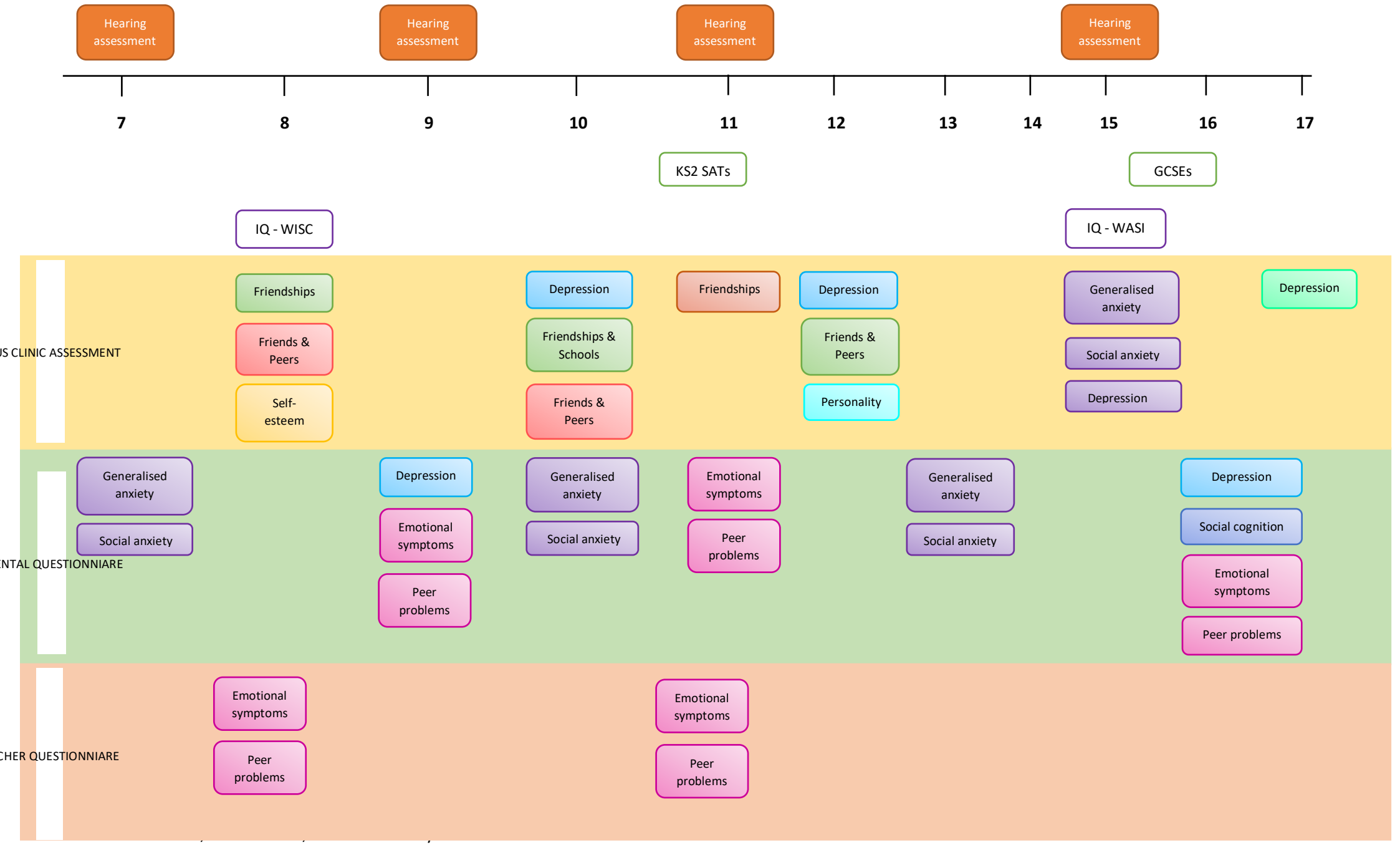
While standard measures of educational achievement and cognition were available in ALSPAC, there were many different measures of psychosocial functioning and mental health used at the different time points. The selection of measures used in this thesis was based on the time point that the measures were taken in order to ensure that the exposure preceded the outcome, repeat of this measure at an appropriate time point and measures being based on self-report rather than parent or teacher report due to importance being placed on the need to collect youth self-reported data to detect internalising problems (Aebi et al., 2017; Hope et al., 1999). Figure 7.3 displays a timeline of ALSPAC measures carried out in relation to mental health/psychosocial development.

Common measures used to assess psychosocial functioning and mental health to ensure repeated measures were the Development and Well-Being Assessment (DAWBA) (Goodman et al., 2000), the Strengths & Difficulties Questionnaire (SDQ) (Goodman, 1997) and the Cambridge Hormones and Mood Project (CHAMP) (Goodyer et al., 1989; Goodyer et al., 1990). Although the SDQ is commonly

used to assess child behaviour, all of the SDQ measures in ALSPAC were either parent or teacher reported and as the focus is on internalising behaviours, the SDQ measures were not seen as the most suitable. The DAWBA and CHAMP measures consisted of self-reported data collected during focus clinics, however the questions asked in the CHAMP questionnaire revolved around satisfaction with the number of friends the child had and how often they saw them outside of school and were more related to their relationship with friends as opposed to measuring aspects of their mental health. Furthermore, these measures were mainly conducted at earlier time points. The DAWBA measures consisted of both parent report at the earlier time points and self-report at a later time point. The DAWBA measured and made diagnoses on various psychopathologies including internalising disorders such as depression and anxiety. While the DAWBA measures included parent reported data, this was a consistent measure used in ALSPAC and the measures taken at 10 and 15 years also coincided with the educational measures at these years. Therefore, the DAWBA was selected to assess mental health outcomes in this thesis. However, at 10 years, the Short Moods and Feelings Questionnaire (SMFQ) (Angold et al., 1995) was selected as a measure of depression as this was self-reported.

IQ was measured at ages 8 and 15 in ALSPAC, so could only be studied at age 15 in this thesis. This was to ensure that the exposure preceded the outcome as with long-term OM related HL being defined as experiencing CHL at two or more time points, all outcomes studied had to be assessed after 9 years. There was therefore no repeated measure of IQ appropriate for this study and hence, which is why IQ is only displayed at this one time point in Figures 7.1 and 7.2.

The selected outcome measures are described in more detail below.


Hearing assessment
Hearing assessment
Hearing assessment
Hearing assessment
7
8
9
10
11
12
13
14
15
16
17
KS2 SATs
GCSEs
IQ - WISC
IQ - WASI
US CLINIC ASSESSMENT
Friendships
Friends & Peers
Self-esteem
Depression
Friendships & Schools
Friends & Peers
Friendships
Depression
Friends & Peers
Personality
Generalised anxiety
Social anxiety
Depression
Depression
ENTAL QUESTIONNIARE
Generalised anxiety
Social anxiety
Depression
Emotional symptoms
Peer problems
Generalised anxiety
Social anxiety
Emotional symptoms
Peer problems
Generalised anxiety
Social anxiety
Depression
Social cognition
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Peer problems
CHER QUESTIONNIARE
Emotional symptoms
Peer problems
Emotional symptoms
Peer problems

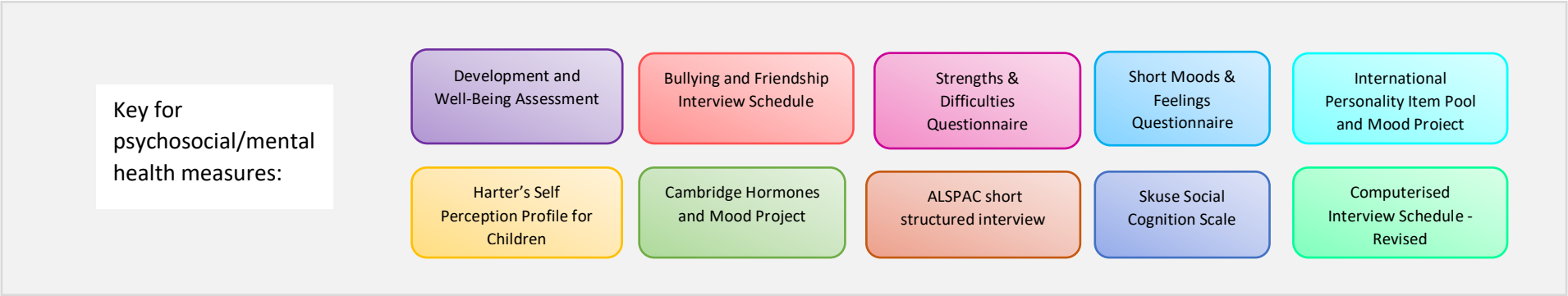

Figure 7.3 Measures of psychosocial functioning and mental health taken at each time point in ALSPAC

7.4.1.1 Mental health measures

Measures of mental health relating to anxiety and depression were collected at ages 10 and 15 years in ALSPAC. Anxiety was assessed using the DAWBA at both 10 and 15 years (Goodman et al., 2000). Depression at age 15 was also assessed using the DAWBA. At age 10, depression was assessed using the SMFQ (Angold et al., 1995). The parental version of the DAWBA was used at 10 years in a questionnaire completed by mothers and self-report at age 15 during a focus clinic interview. Depression was assessed during clinic interviews with the child at both ages.

7.4.1.1.1 The Development & Well-Being Assessment

The DAWBA is a collection of questionnaires used to measure common areas of child and adolescent psychopathology (Goodman et al., 2000). It was designed to generate psychiatric diagnoses in 5-16-year olds according to ICD-10 and DSM-IV criteria (WHO, 1993) (APA, 1994). It was suggested that the DAWBA had substantial potential as both an epidemiological measure and clinic assessment from an initial validation study (Goodman et al., 2000). Subsequent studies have utilised the DAWBA and it has also been used in all British nationwide surveys of child and adolescent mental health (Meltzer et al., 2003).

Each section of the DAWBA specific to a certain psychopathology is comprised of structured and open-ended questions and is scored out of 12. A computerised diagnostic algorithm is used to predict how likely it is that an experienced clinical rater would assign the child with an operationalised to ICD-10, DSM-IV or DSM-V diagnosis. This prediction is outputted as one of six probability bands which range from a probability of less than 0.1% likely to over 70% likely (see https://dawba.info/d0.html for more information).

In ALSPAC, the questions used asked about all the symptoms and other criteria needed to make a diagnosis according to ICD-10 and DSM-IV criteria and computer predicted diagnoses were reviewed by senior clinical psychiatrists (Siebald et al., 2016; Hammerton et al., 2013).

7.4.1.1.1.1 Anxiety

Anxiety was assessed using the DAWBA at both 10 and 15 years. The DAWBA assesses different types of anxiety disorder. These include generalised anxiety and social anxiety disorder which were obtained as measures of anxiety for this research.

7.4.1.1.1.2 Generalised anxiety

Generalised anxiety disorder (GAD) is characterised by ongoing anxiety and worry about many events and thoughts (Gale and Davidson, 2007). Questions relating to generalised anxiety were revolved around feelings of worry in general. Children were asked about experiencing symptoms of GAD over the last 6 months. Questions asked included:

- "Do you ever worry?"
- "Thinking about the last 6 months, and comparing yourself with other people of your age, have you worried about…
    - Past behaviour: Did I do that wrong? Have I upset someone? Have they forgiven me?
    - School work, homework or examinations?
    - Disasters: Burglaries, muggings, fires, bombs etc
    - Your own health
    - Bad things happening to others: family, friends, pets, the world (e.g. wars)

- The future: e.g. changing school, moving house, getting a job, getting a boy/girlfriend
- Making and keeping friends
- Death and dying
- Being bullied or teased
- Your appearance or weight
- Other specific worry: (describe)

If children answered yes to any of these questions they were then asked if they find it difficult to control the worry and about consequences of the worrying such as:

- Does worrying lead you to feeling restless, keyed up, on edge, or unable to relax?
- Does worrying lead you to feeling tired or 'worn out' more easily?
- Does worrying lead to difficulties in concentrating or to your mind going blank?
- Does worrying lead to irritability?
- Does worrying lead to you feeling tense in your whole body?
- Does worrying interfere with your sleep, e.g. difficulty in falling or staying asleep, or restless, unsatisfying sleep?

They were asked how upset or distressed they get over worrying and if the worrying interferes with how well they get on with the rest of the family, making and keeping friends, learning or class work, playing, hobbies, sports or other leisure activities and if these worries had made it harder for those around them (family, friends, teachers etc). The questionnaire was deemed to be relevant as interference from anxiety with making and keeping friends for example, may reflect difficulties with social interaction. The full questionnaire can be found in Appendix C.

7.4.1.1.1.3 Social anxiety

As HL may influence communication, anxiety may be more pronounced in relation to social situations, so the measure of social anxiety was also selected. Questions surrounding social anxiety were based on a fear of social situations. Social anxiety disorder (SAD, previously termed social phobia) is characterised by a "marked and persistent fear of social or performance situations" (Brook and Schmidt, 2008). Individuals with SAD have a fear of a range of social interactions, including conversations with strangers, joining in groups or speaking on the telephone (Leigh and Clark, 2018). It is the third most common mental health condition next to depression and substance abuse occurring in around 13% of the population and usually begins in childhood or adolescence with age of onset of 10 to 13 years (Leigh and Clark, 2018; Jefferson, 2001). People with SAD generally tend to avoid important activities such as school and work and if they do attend, they do not participate. This avoidance can result in lower achievements which result in decreased occupational, academic and family function (Leigh and Clark, 2018; Jefferson, 2001). SAD can therefore result in chronic distress and is associated with other disorders including other anxiety disorders, depression and substance abuse disorders (Brook and Schmidt, 2008).

The fear of social situations section of the DAWBA used in ALSPAC asked about experiencing social anxiety overall and then specifically over the last 4 weeks. Questions asked included:

- Overall, do you particularly fear or avoid social situations that involve a lot of people, meeting new people, or doing things in front of other people?

- Have you been particularly afraid of any of the following social situations over the last 4 weeks?
    - Meeting new people?
    - Meeting a lot of people, such as at a party?

- Eating in front of others?
- Speaking in class?
- Reading out loud in front of others?
- Writing in front of others?

- Most young people are attached to a few key adults, feeling more secure when they are around. Some young people are only afraid of social situations if they don't have one of these key adults around. Other young people are afraid of social situations even when they are with one of these key adults. Which is true for you?

    - Are you just afraid with adults or are you also afraid in situations that involve a lot of young people, or meeting new people of your own age?
    - Outside of these social situations, are you able to get on well enough with the adults and young people you know best?

- Is the main reason you dislike social situations because you are afraid you will act in a way that will be embarrassing or show you up?

- Do you dislike social situations because of specific problems with speaking, reading or writing?

- When you are in one of the social situations you are afraid of, do you normally…
    - Blush (go red) or shake (tremble)?
    - Feel afraid that you are going to be sick (throw up)?
    - Need to rush off to the toilet or worry that you might be caught short?

    - When you are in one of the social situations you are afraid of, or when you think you are about to come up against one of these situations, do you become anxious or upset?
- How often does your fear of social situations result in you becoming upset like this?

- Does your fear lead to you avoiding social situations?
- Does this avoidance interfere with daily life?
- Do you think your fear of social situations is over the top or unreasonable?
- Has your fear of social situations made it harder for those around you (family, friends, teachers etc.)?

These questions pertaining to social anxiety were deemed relevant due to covering problems with speaking, reading and writing which may be exhibited by children with HL, and in turn acting in a way that may be embarrassing. The full questionnaire can be found in Appendix C.

7.4.1.1.1.4 Depression

The DAWBA section on depression asked questions pertaining to the child's mood over the last 4 weeks. Questions included:

- In the last 4 weeks have there been times when you have been very sad, miserable, unhappy or tearful?
- Over the last 4 weeks has there been a period when you have been really miserable nearly every day?
- When you have been miserable, could you be cheered up?

- In the past week when you felt sad, miserable or depressed did you ever become
- happier when something nice happened or when you were in company?

Questions were also asked about irritability, loss of interest, eating, sleeping habits, their thoughts, self-harm and interference with family, friends and learning and class work. The full questionnaire can be found in Appendix C.

These questions asked as part of the DAWBA covered areas relating to social interactions, worry in general, school activities, emotions and relationships with friends and family, making the DAWBA a better suited measure as opposed to the SDQ or CHAMP.

7.4.1.1.2 The Short Moods and Feelings Questionnaire

The Short Moods & Feelings Questionnaire (SMFQ) was administered to children aged 10 in the ALSPAC cohort who attended the focus clinic. The SMFQ is a 13-item scale of depression (Angold et al., 1995). The scale is based on the DSM-III criteria for depression (American Psychiatric Association, 1980). While the DAWBA predicts diagnoses of depression, the SMFQ gives an indication of depressive symptoms. The child is presented with 13 phrases and is asked to rate how indicative each phrase is of how they have been feeling over the past two weeks. A score out of 26 is given and a score of 11 or higher can indicate that a child is suffering from depression (Thapar and McGuffin, 1998).

In ALSPAC at the 10-year clinic, the children were given a series of envelopes with statements from the SMFQ written on them about how they might have been feeling or acting in the previous two weeks. A psychologist administering the assessment read the statement out loud and the child was asked to post each statement into one of three boxes which contained the responses. The child had

to post the envelope in the box which best described how they felt about the statement. The responses were 'True, 'Sometimes' and 'Not at all'.

The statements presented to the children included:

- Example: "I have felt energetic"

1. "I felt miserable or unhappy"
2. *"I have been having fun"*
3. "I didn't enjoy anything at all"
4. "I felt so tired I just sat around and did nothing"
5. "I was very restless"
6. "I felt I was no good anymore"
7. "I cried a lot"
8. *"I felt happy"*
9. "I found it hard to think properly or concentrate"
10. "I hated myself"
11. *"I enjoyed doing lots of things"*
12. "I was a bad person"
13. "I felt lonely"
14. "I thought nobody really loved me"
15. "I thought I could never be as good as other kids"
16. "I did everything wrong"
17. *"I have had a good time"*

The example statement and statements 2, 8, 11 and 17 were positive dummy statements included to balance out the negative statements and were not used when deriving the depression score.

Each phrase was scored according to the answer given by the child : “not at all” (scored 0), “sometimes” (scored 1) and “true” (scored 2). The scores were summed to give a total score out of 26 with higher scores indicating greater depression (Kwong, 2019).

7.4.1.2 Educational achievement measures

ALSPAC has linkage to educational data from the National Pupil Database provided by the Department of Education in England. This includes data on Key Stage 2 (KS2) Standardised Attainment Test (SAT) grades at age 11 and General Certificate of Secondary Education (GCSE) test grades at age 16.

KS2 SATs and GCSEs are compulsory examinations for all children attending state-funded schools in England and are optional for those attending independent schools. KS2 SATs are taken when the child is 10/11 years old, when they are at the end of Key Stage 2, before moving on to Key Stage 3. GCSEs are taken at the end of Key Stage 4 when the child is 15/16 years old. These mark the end of their secondary education and grades may determine the next step in their education. For example, in order to study and obtain Advanced Level Qualifications (A levels) which are a general requirement to obtain a university degree, five GCSEs at grades A*-C are generally required (UCAS, 2019).

These grades will act as markers of educational achievement as they were obtained from standardised assessments that were administered nationally. The average grade that could be obtained in KS2 SATs was a Level 4 and for GCSEs these ranged between grades A* to C, with A* being the highest that one could achieve. The data will be analysed to see if children obtained a level 4 or above in KS2 English, Maths and Science and if they obtained 5 or more A*-C GCSE grades.

7.4.1.3 Cognition measures

Cognitive ability in ALSPAC was assessed using the Wechsler Scales of Intelligence. As noted in chapter 4, the Wechsler Scales of Intelligence are standardised assessments of intelligence, which give a score for intelligence quotient (IQ). The IQ score is a measure of general cognitive ability which quantifies intelligence relative to age (Gottfredson, 1997). As IQ is a standardised measure of intelligence and has been used as a measure of cognition in previous studies, IQ in ALSPAC was also selected as a measure of cognition as it is a valid measure and would allow comparison with other studies. The use of IQ as an appropriate measure of cognition was discussed in more detail in chapter 4, including the mention of IQ being strongly linked to educational and social outcomes (Matzel and Sauce, 2017).

As mentioned earlier, in this thesis associations between long-term OM related HL and IQ at age 15 years only will be studied. IQ at age 15 was assessed using the Wechsler Abbreviated Scales of Intelligence (WASI) (Wechsler, 1999). The WASI was produced as a reliable and valid brief measure of intelligence for 6 to 89-year olds. Although a brief measure, the WASI still produces an estimate of full-scale (total) IQ as well as an estimate of verbal IQ and performance IQ, like the other full standardised Wechsler intelligence tests. The WASI consists of four subtests – two each for testing verbal IQ and performance IQ which cover verbal knowledge, visual information processing, spatial and nonverbal reasoning, and crystallised and fluid intelligence. The verbal subtests include a Vocabulary and a Similarities test, while the performance subtests include a Block design test and a Matrix reasoning test (Saklofske et al., 2000). However, in ALSPAC, only the Vocabulary and Matrix reasoning subtest were carried out and these were used to estimate a full IQ score.

7.4.1.4 Confounders

This section outlines the measures used in ALSPAC to derive information on the confounding factors identified in section 3. Most data were taken from files created at birth and parental questionnaires and are detailed below.

7.4.1.4.1 KZ file

A file known as the KZ file was created containing basic information on all children from each ALSPAC pregnancy, abstracted from medical records. This included the sex of the child, congenital defects, causes of foetal death, gestation at delivery, birth weight and other measures. Information relating to the sex and congenital defects of the child was obtained from this file to include in analyses.

7.4.1.4.2 Parental questionnaires

Data in relation to ethnicity, socioeconomic group, maternal education and parental smoking were obtained from various questionnaires sent to mothers and their partner's during pregnancy and postnatally at different time points. The derivation of each of these variables is explained below:

7.4.1.4.2.1 Ethnicity

Questions regarding the mother's ethnicity, her partner's ethnicity and the child's ethnicity were asked in a questionnaire sent to the mother during pregnancy when she was 32 weeks. The child ethnicity variable was selected to be used in analyses. As the ALSPAC sample is predominantly white, ethnicity was categorised as either 'white' or 'non-white'.

7.4.1.4.2.2 Maternal education

Information on mother's highest qualification was also obtained through the questionnaire sent to mother's during pregnancy at 32 weeks' gestation. Mothers were asked to indicate any qualifications that they had obtained ranging from CSE to degree level and included vocational qualifications as well as no qualifications. Each mother's highest qualification was then derived.

7.4.1.4.2.3 Socioeconomic group

Socioeconomic group was derived from data on education and occupation obtained from the maternal questionnaire completed during pregnancy (32 weeks gest). The data was used to derive a socio-economic group variable based on the 1951 Socio-economic Group (SEG) classification (Rose and Pevalin, 2001). The data covered the current employment status of the mother and her partner as well as for both their mothers and their partners. Details of the occupation such as trade or profession and type of industry or service provided were also obtained and used to classify the mother and her partner into socioeconomic groups. People with jobs of similar social and economic status are brought together by this Socioeconomic Group classification (Rose and Pevalin, 2001).

During the 20th century, the main social class classification was the Registrar General's Social Class (RGSC) scheme. The RGSC was based on the assumption that society is an ordered hierarchy of occupations graded according to skill and aimed to bring together people of similar occupational skill. This reflected society being a hierarchy of inherited natural skills shown through the differing levels of occupational skill needed for different occupations (Rose and Pevalin, 2001). The classification consisted of 5 categories. Nonetheless, due to limitations including that of the RGSC

being created based on an industrialist society and economy in the nineteenth century at a time prior to significant emerging of theoretical social science in Britain, the RGSC was seen to be inadequate. Hence, it was seen as outdated and having no theoretical basis (Rose and Pevalin, 2001).

Socio-economic Group (SEG) was another classification put forward in 1951 by social scientist David Glass. This classification also presented with its limitations as it failed to explain its conceptual basis. Furthermore, the SEG grouping consisted of 17 classes and as there was no set conceptual basis, when it came to analysing the data, researchers did not have any set guidance as to how best breakdown and analyse the data. It could not be collapsed into the RGSC classes, as it was a different measure. Like RGSC, it also rested on outdated discrepancies such as skill. However, rather than just looking at occupation, SEG took into account employment status and size of employing organisation and was seen as a more social scientific measure, compared to the RGSC (Rose and Pevalin, 2001).

The Socio-economic Groups are presented in Table 7.1.

Table 7.1 Socioeconomic group (1951) classification

(1.1) Employers in industry, commerce, etc (large establishments)
(1.2) Managers in central and local government, industry, commerce, etc (large establishments)
(2.1) Employers in industry, commerce, etc (small establishments)
(2.2) Managers in industry, commerce, etc (small establishments)
(3) Professional workers - self-employed
(4) Professional workers - employees
(5.1) Intermediate non-manual workers - ancillary works and artists
(5.2) Intermediate non-manual workers - foremen and supervisors non-manual
(6) Junior non-manual workers
(7) Personal service workers
(8) Foremen and supervisors - manual
(9) Skilled manual workers
(10) Semi-skilled manual workers
(11) Unskilled manual workers
(12) Own account workers (other than professional)
(13) Farmers - employers and managers
(14) Farmers - own account
(15) Agricultural workers
(16) Members of armed forces
(17) Inadequately described and not stated occupations

When used in research, for analytical purposes, these 17 groups are commonly collapsed into smaller categories, similar to that of the best-known and more recent social class classification, the Goldthorpe Class schema which consists of seven categories (Erikson and Goldthorpe, 1992). The Goldthorpe schema has been validated as a good predictor of health and educational outcomes. The NS-SEC classification used today is based on this schema. When analysing SEG for this thesis, the 17 categories will be collapsed into categories similar to those of the NS-SEC, as presented in Table 7.2. Categories within the SEG classification were grouped together into groups based on the NS-SEC classification with the lower supervisory and technical operations class being omitted.

Table 7.2 Re- classification of SEG for analysis based on NS-SEC classification

I– Managerial & professional occupations
II – Intermediate occupations
III – Small employers & own account workers
V Semi routine & routine occupations

1.1.1.1 Parity

Questionnaires sent to mothers during pregnancy asked if this was their first pregnancy and if not, asked their number of previous pregnancies. This information was used to determine number of siblings.

7.4.1.4.2.4 Parental smoking

Questionnaires sent to mothers during pregnancy and when their child was 7 years old asked about their smoking habits. Their partners were asked about their smoking habits in questionnaires sent to

them at 7 years and 12 years. The variables derived relate to how many cigarettes were smoked per day.

7.4.1.4.2.5 Index of Multiple Deprivation

The census-derived Index of Multiple Deprivation (IMD) (2000) was used in ALSPAC to relatively measure deprivation of neighbourhoods and was selected to be used in analyses to indicate social deprivation at age 7. The IMD uses a range of information from local government and other sources to create a measure of deprivation from which the areas are ranked (Jordan et al., 2004). This along with maternal education and SEG were selected as socioeconomic factors.

7.4.2 Sample selection

15,645 children took part in ALSPAC, however not all of these had their hearing assessed. Hence, the sample included only those children who attended the focus clinic sessions and had their hearing assessed. This ranged from 7,761 children at 7 years to 4,730 children at 15 years. As the focus was on the impact of *long-term* OM related hearing loss, which was defined as having OM related hearing loss at two or more of the time points (7 years, 9 years, 11 years and 15 years), the sample for these analyses consisted of children who had their hearing assessed at 2 or more of the time points. This was a sample of 7,795 children. Children who were likely to have had SNHL at any of the time points were excluded, leaving a sample of 7,737 children as presented in the previous chapter.

For each outcome analysed the sample consisted of children who attended the focus clinics at ages prior to the age of the outcome being measured. E.g. for outcomes measured at 10 years, the

sample consisted of children who had their hearing assessed at ages 7 & 9 years. For outcomes measured at 15 and 16 years, the sample consisted of children who had their hearing assessed at any two of the 7, 9 ,11 and 15-year clinics. Due to this and the availability of data for each outcome variable, the sample number for each outcome measure varied. Furthermore, sample sizes could not be determined prior to obtaining the data and determining the exposure sample. Figures 7.4 and 7.5 explain the sample selection procedures for outcomes at 10/11 years and outcomes at 15/16 years.

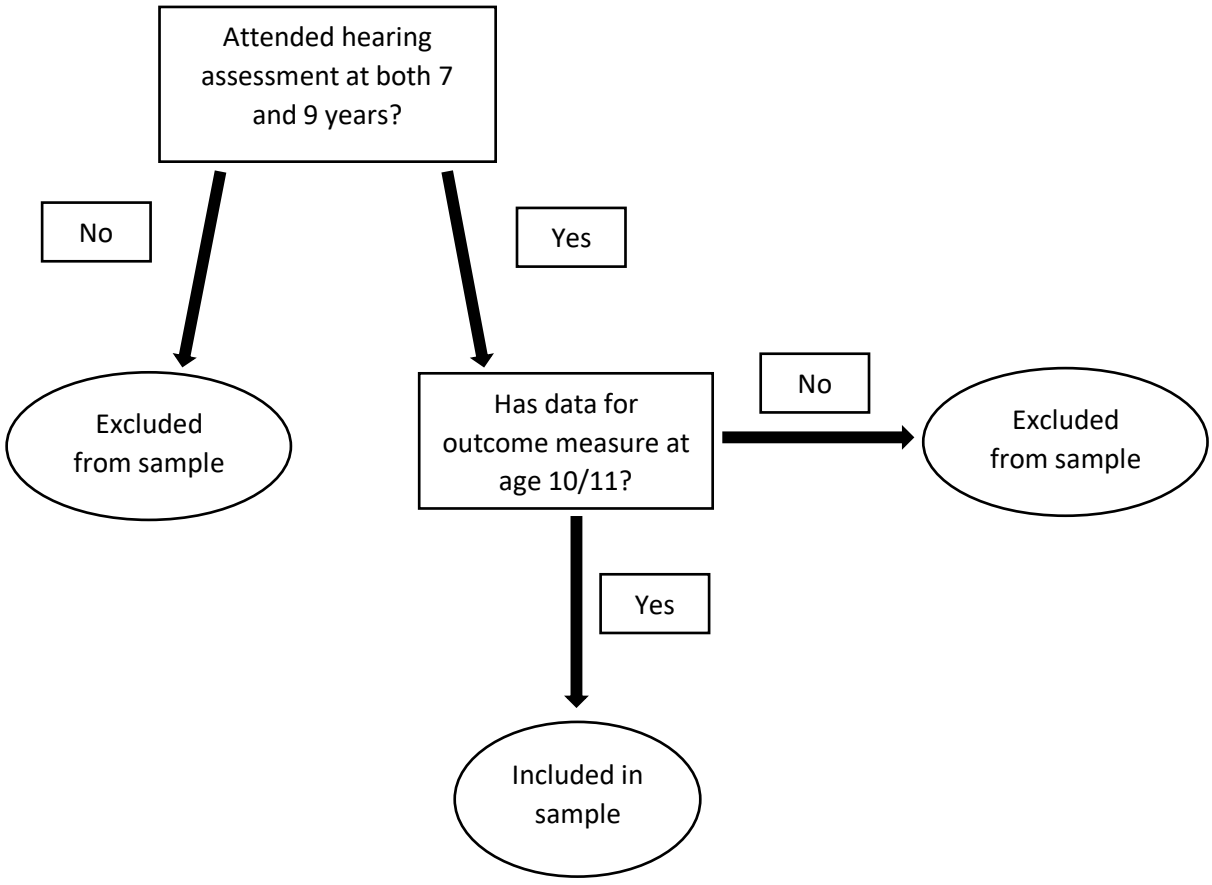

Figure 7.4 Sample selection for analysing associations between long-term OM related HL and 10/11 year outcomes in ALSPAC

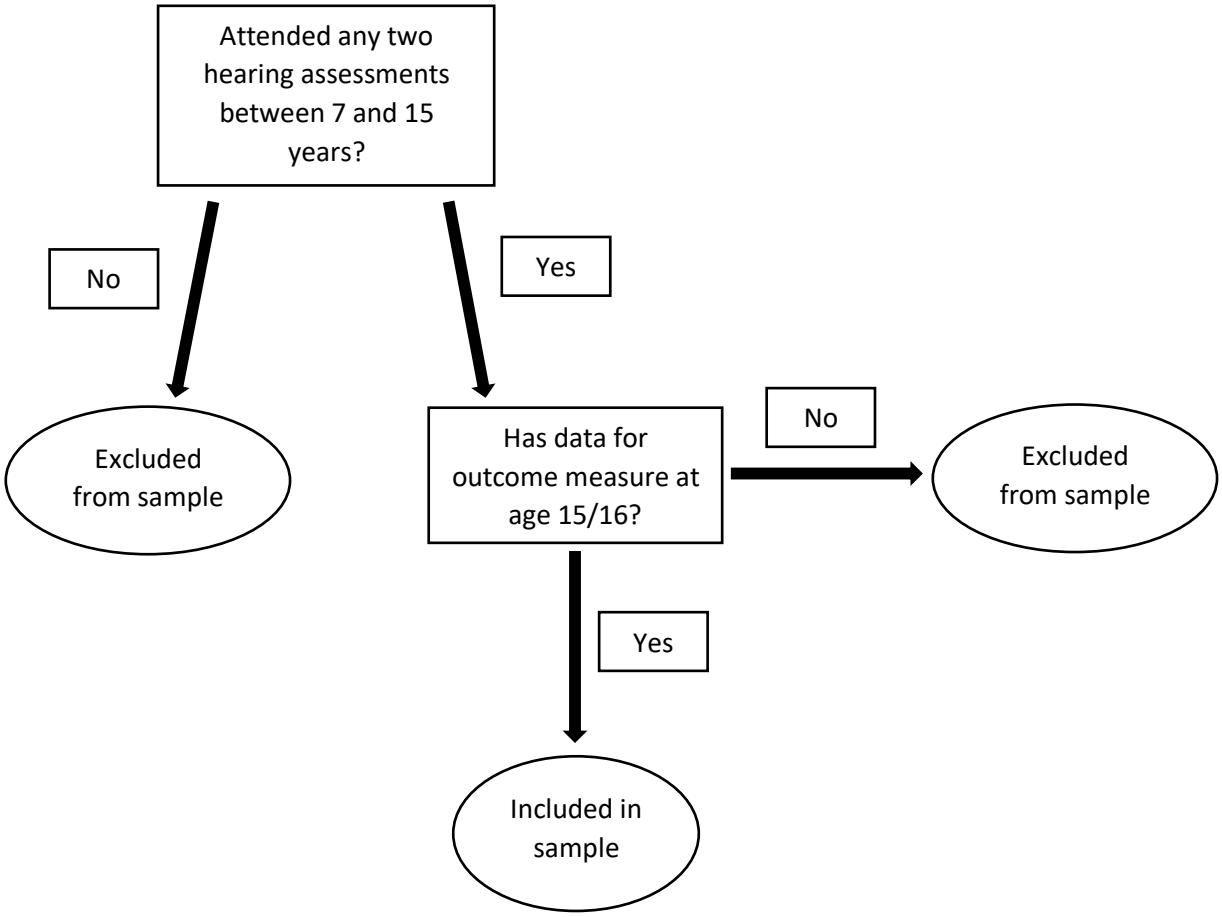

Figure 7.5 Sample selection for analysing associations between long-term OM related HL and 15/16 year outcomes in ALSPAC

7.4.3 Methods of data analysis

7.4.3.1 Software

The data was analysed using Stata/IC 15.1 (StataCorp, College Station, TX).

7.4.3.2 Data checking and assumptions

The previous two chapters described the hearing data available in ALSPAC which had been analysed in order to report on the available hearing data in ALSPAC and to use this data to estimate the prevalence of long-term OM related HL. In order to analyse the associations between long-term OM related HL and outcomes, the outcome and potential confounding variables were first analysed visually via tabulation and graphical presentation of the data to identify anomalies or outliers and to ensure that observations were coded and categorised appropriately. Missing values were also checked to be coded correctly as missing. The frequency distributions of continuous variables were checked for normality. Continuous variables consisted of IQ at 15 years and depression at 10 years.

7.4.3.3 Tests of data assumptions

Analyses of the associations between long-term OM related HL were carried out using linear and logistic regression models. The data were first analysed to test the data assumptions made by these regression models. Most of the outcome and confounding variables analysed were categorical, therefore analyses used logistic regression models which do not make assumptions of linearity and normality of the data. Associations with continuous variables are tested using linear regression models which of course assume that the relationship between the independent variable and dependent variable is linear. The independent variable in this study was binary – whether the child had long-term OM related HL or not, hence linearity was achieved as with a binary variable the two values of the independent variable lie on a straight line.

Linear regression models also assume that the residuals are normally distributed. The residuals refer to the differences between the observed outcome values and the values predicted by the regression model (Kirkwood and Sterne, 2003). Inverse normal plots were produced to analyse the distribution of the residuals for IQ at 15 years and depression at 10 years. Inverse normal plots are scatter plots

that compare the values of the observed distribution with the corresponding points of the normal distribution. The plot of data is linear if the data are normally distributed and curved if they are not.

Linear regression models also hold the assumption that the variance of the residuals is constant across each value of the independent variable, that is that the data is homoscedastic. A plot of the residuals against the predicted (fitted) values was plotted to study the variability of the residuals.

For both adjusted linear and logistic regression models, multicollinearity of the independent variables included in the adjusted models was tested. Multicollinearity refers to the independent variables being correlated with each other which leads to the regression model estimates becoming unstable with standard errors becoming widely inflated (Yoo et al., 2014). The absence of multicollinearity was assessed using variance inflation factors (VIF) in Stata. Variables with a VIF of greater than 10 indicate high multicollinearity with other variables in the dataset (Yoo et al., 2014; Midi et al., 2013). Tolerance values are also provided which equate to 1/VIF. Tolerances of less than 0.1 are indicative of high multicollinearity (Myers, 1990).

Other assumptions underlying logistic regression models relate to the dependent variable being a binary variable and the observations being independent from each other. These assumptions were met as the outcome variables were dichotomised and the data observed for one individual was not dependent on the data observed for another individual. The model also assumes linearity of the independent variable and log odds, however as the long-term OM related HL exposure variable was binary, checks for its linearity with log odds were not necessary.

7.4.3.4 Data categorisation

Variables that were not categorised appropriately for analyses were then re-categorised. E.g. variables were dichotomised if they were not already if they were to be analysed as a binary variable.

7.4.3.5 Statistical analysis

7.4.3.5.1 Regression models

Education and mental health outcome variables were binary categorical variables thus were analysed using logistic regression models. The IQ variables were analysed as continuous variables using linear regression models.

Unadjusted effect sizes were obtained by running the analyses with the single long-term OM related HL predictor variable. Following the unadjusted analyses, adjusted analyses were carried out to control for any confounding effects from potential confounding factors. These were sex, ethnicity, maternal education, socio-economic group (SEG), social deprivation, and maternal smoking during pregnancy and at 7 years. Each model was run with the addition of these predictor variables.

7.5 Results

7.5.1 Sample

Table 7.3 describes the number of children in the exposure sample with data for each outcome. As can be seen, the number presented for number of children with data for Key Stage 2 SATS was considerably smaller than the rest of the rest of the outcomes. This was due to limited data availability for KS2 SATS for the whole ALSPAC cohort. Due to the small number of outcome data for these variables, these variables were excluded from analyses.

Table 7.3 Number of children in ALSPAC in the exposure sample with outcome data

Outcome	Age (years)	Sample n	Long-term OM related HL (%)	No long-term OM related HL (%)
Achieved Level 4 or above English	10/11	936	20/24 (83.33%)	840/912 (92.11%)
Achieved Level 4 or above in Maths	10/11	936	21/24 (87.50%)	826/912 (90.57%)
Achieved Level 4 or above in Science	10/11	936	21/24 (87.50%)	878/912 (96.27%)
Generalised anxiety	10	5,137	0/92 (0.00%)	22/5,045 (0.44%)
Social anxiety	10	5,153	0/93 (0.00%)	16/5,060 (0.32)
Depression	10	6,836	9/102 (8.82%)	307/5,383 (5.70%)
GCSEs (achieved 5 or more A*-C grades)	15/16	6,375	117/178 (65.73%)	4,339/6,197 (70.02)
Generalised anxiety	15	5,154	1/153 (0.65%)	38/5,000 (0.76%)
Social anxiety	15	5,006	0/154 (0.00%)	39/5,006 (0.78%)
Depression	15	5,158	1/154 (0.65%)	80/5,004 (1.60%)
Outcome	**Age**	**Sample n**	**Mean for children with long-term OM related HL (95% CI)**	**Mean for children without long-term OM related HL (95% CI)**
IQ				
Verbal	15	5,113	89.79 (87.03, 92.56)	93.90 (93.42, 94.38)
Performance	15	5,108	93.41 (91.23, 95.60)	95.22 (94.87, 95.60)
Total	15	5,107	91.56 (89.39, 93.72)	94.62 (94.25, 94.98)

7.5.2 Data checking and assumptions

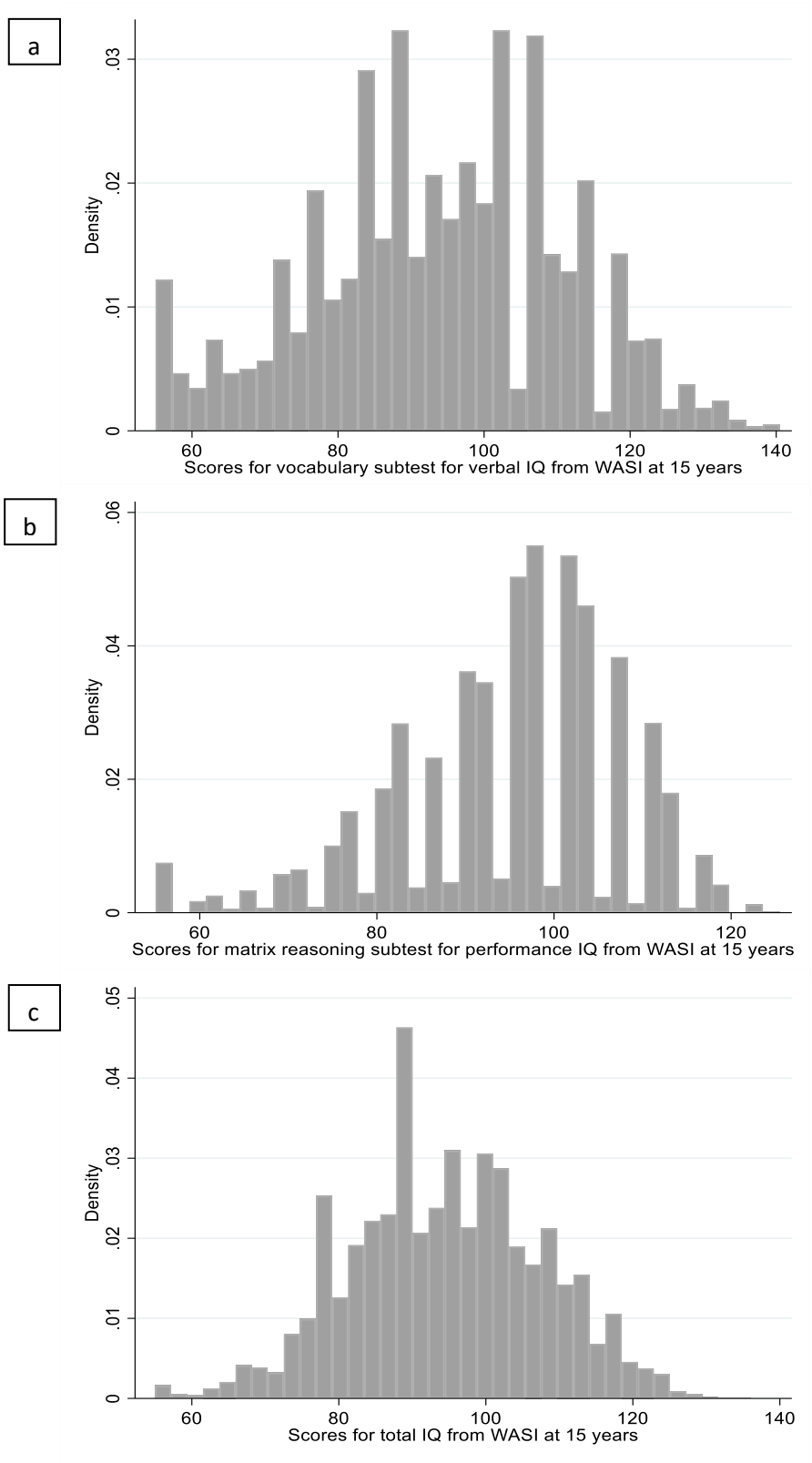

Figure 7.6 Frequency distributions of IQ variables in ALSPAC at 15 years:
a) Scores for vocabulary subtest of Verbal IQ
b) Scores for matrix reasoning subtest of Performance IQ
c) Scores for Total IQ representing total of vocabulary and matrix reasoning subtests

Figure 7.6 presents the frequency distributions for the IQ variables at age 15. IQ scores are highly standardised to yield a normal distribution with a mean of 100 and standard deviation of 15. The verbal IQ and performance IQ data in ALSPAC at age 15 deviate slightly from the normal distribution, however the total IQ data follows a near normal distribution. This was looked into by the ALSPAC team and it was concluded that although WASI is a reliable estimate of intelligence, in this population the scores from WASI are an underestimate of IQ.

The distribution for the 10-year depression variable was found to be positively skewed and data was not normally distributed as shown in Figure 7.7. Only a small number of children had high scores for depressive symptoms at age 10 in ALSPAC.

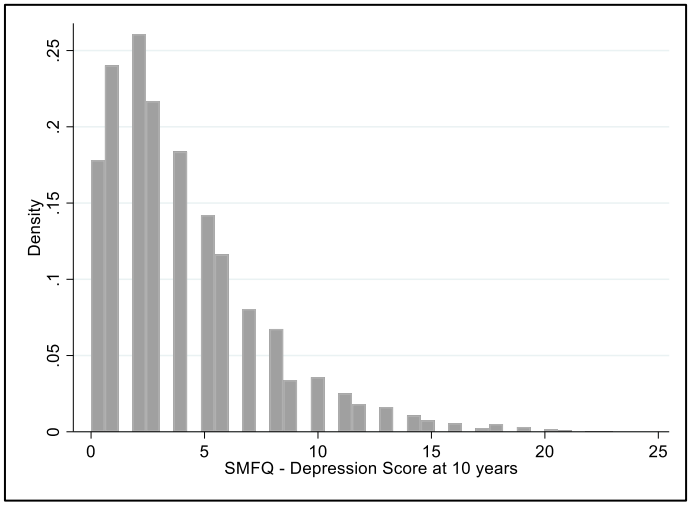

Figure 7.7 Frequency distribution of depression score in ALSPAC at 10 years

As the data for the IQ variables followed a normal distribution, their residuals also followed a normal distribution with their inverse normal plots appearing linear.

As the data for depression at 10 years did not follow a normal distribution, the distribution of the residuals was also not normal as shown in Figure 7.8 which shows that the plot of residuals is slightly curved and does not meet the corresponding points of the normal distribution at the extremes.

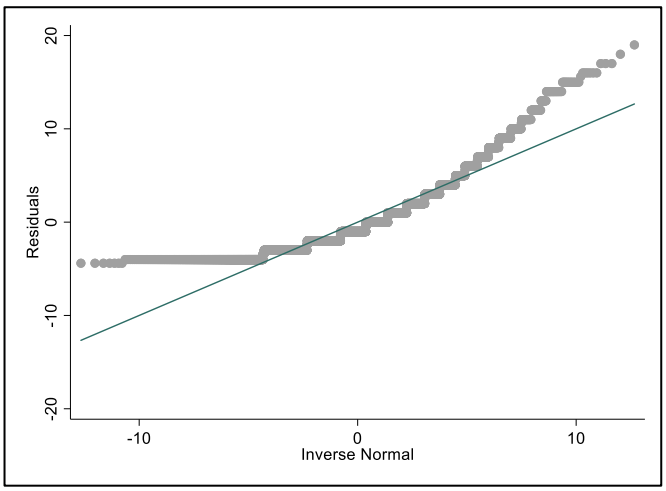

Figure 7.8 Inverse normal plot of observed distribution of residuals for depression at 10 years in ALSPAC

Linear regression models also hold the assumption that the variance of the residuals is constant across each value of the independent variable, that is that the data is homoscedastic. Figure 7.9 presents a plot of the residuals against the predicted (fitted) values for the depression at 10 years data. As we only have two values of the independent variable, residuals are plotted at these two points. The plot shows that the variance in the residuals is fairly constant and does not change much

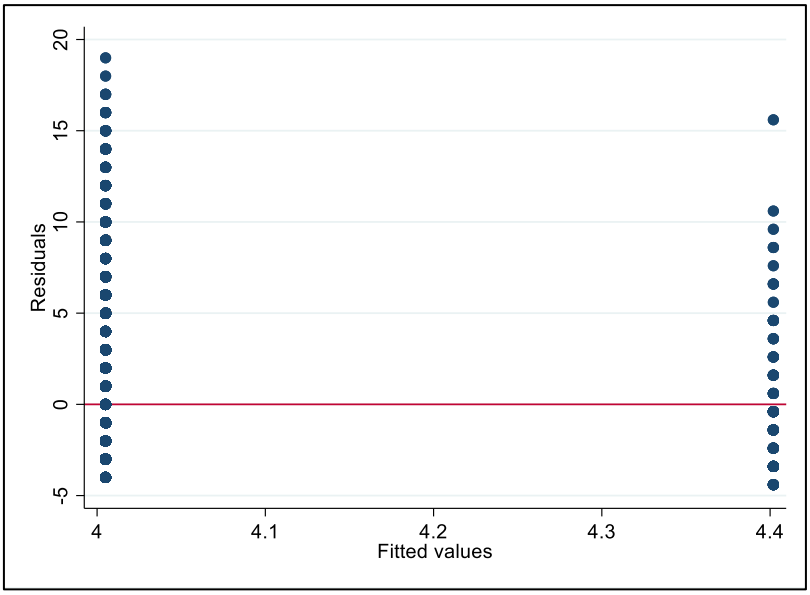

Figure 7.9 Plot of residuals against fitted values for depression at 10 years in ALSPAC

with the increasing value of the independent variable. White's test for heteroskedasticity was also used to assess the homogeneity of the variance in residuals (White, 1980). The test gave a p value of 0.4301 meaning that the null hypothesis of the variance being homogenous could be accepted.

VIFs assessing the absence of multicollinearity were presented for all variables included in the model. All variables to be included in the adjusted models were found to have VIF values of less than 10 with a mean of 1.10 and tolerance values of less than 0.1, indicating that multicollinearity was minimal or absent.

7.5.3 Data categorisation

The depression at 10 years variable did not completely meet the assumptions for linear regression. This did not mean that the model could not be used but meant that the reliability of effect presented would be reduced. The variable was dichotomised and analysed using logistic regression models as were the rest of the mental health outcome variables. The depressive symptoms score given to participants was out of 26, with a score of 11 or more indicating presence of depressive symptoms. Therefore, the depression at 10 years variable was dichotomised so that scores <11 indicated no depressive symptoms and a score of 11 or greater indicated depressive symptoms. The variable has also been treated this way in other studies (Angold et al., 2002; Patton et al., 2008; Stansfeld et al., 2004; Turner et al., 2014). Hence, all outcome variables with the exception of IQ were categorical variables and were dichotomously coded.

Both exposure and educational and mental health outcome variables were dichotomously coded as 'No' (0) and 'Yes' (1) in regard to having:

- Long-term OM related hearing loss (exposure)

- Achieved 5 or more GCSEs at A*-C grade (outcome)
- Generalised anxiety at age 10 or 15 (outcome)
- Social anxiety at age 10 or 15 (outcome)
- Depression at age 10 or 15 (outcome)

7.5.4 Outcomes

As seen in Table 7.3, very few children within the whole sample had anxiety or depression at age 10 with no children with long-term OM related HL presenting with any anxiety. Depression was present in more children with long-term OM related HL than in children without long-term OM related HL at age 10. At age 15, the proportion of children in the whole sample with anxiety and depression increased only slightly but remained low.

Most children in the sample achieved 5 or more A*-C grade GCSEs with fewer children with long-term OM related HL achieving these compared to children without long-term OM related HL.

Mean verbal and total IQ scores at age 15 were lower in children with long-term OM related HL compared to children without long-term OM related HL. There was little difference in mean score for performance IQ. The greater variation in the confidence intervals for the IQ scores of children with long-term OM related HL with both the lower and higher limits being lower than those of children without long-term OM related HL also represents children with long-term OM related HL being likely to score lower than children without long-term OM related HL in the general population.

7.5.5 Regression models

Table 7.4 displays the results of the logistic regression analyses for the mental health and education variables and Table 7.5 displays the results of the linear regression analyses for IQ.

Table 7.4 Odds ratios (OR) for mental health and educational outcomes for children with and without long-term OM related HL in ALSPAC, adjusted for sex, ethnicity, socioeconomic group, maternal education, social deprivation, parity and maternal smoking in pregnancy and at 7 years

Outcome	Unadjusted n	Unadjusted OR (95% CI)	p value	Prob > chi2	Adjusted n	Adjusted OR (95% CI)	p value	Prob > chi2
10-year outcomes								
Generalised anxiety	6,259	1 (omitted)		.	4,071	1 (omitted)		0.0311
Social anxiety	5,006	1 (omitted)		.	4,212	1 (omitted)		0.6872
Depression	6,836	1.57 (0.79, 3.14)	0.201	0.2282	4,347	1.08 (0.39, 3.01)	0.882	0.0002
15-year outcomes								
Generalised anxiety	5,154	0.85 (0.12, 6.26)	0.876	0.8730	3,290	1 (omitted)		0.0388
Social anxiety	5,006	1 (omitted)		.	3,296	1 (omitted)		0.0044
Depression	5,158	0.40 (0.06, 2.91)	0.367	0.2922	3,294	1 (omitted)		0.0578
Achieved 5 or more A*-C GCSE grades	6,375	0.82 (0.60, 1.12)	0.220	0.2243	3,968	0.74 (0.48, 1.14)	0.170	<0.001

7.5.5.1.1 Mental health

As Table 7.3 showed, no children who had long-term OM related HL had any anxiety at 10 years and social anxiety at 15 years. This resulted in the regression analyses presented an OR of 1, indicating that there was no association between long-term OM related HL and these mental health outcomes and therefore, an omitted standard error and confidence intervals. At 10 years, over 8% of children with long-term OM related HL presented with depressive symptoms, however both unadjusted and

adjusted analyses presented with wide confidence intervals crossing an OR of 1 and did not reveal an association between long-term OM related HL and depression at age 10.

One child with long-term OM related HL had generalised anxiety at age 15 and one child with long-term OM related HL had depression at age 15 and adjusted models revealed that there was no association between these two outcomes and long-term OM related HL.

7.5.5.1.2 Education

Most of the children with long-term OM related HL did achieve 5 or more A*-C grade GCSEs (Table 7.3). Both the ORs for unadjusted and adjusted regression models showed that children with long-term OM related HL were more likely not to achieve 5 or more A*-C GCSE grades. Upon adjustment for confounders the OR decreased, however, the wide variability in confidence intervals (which increased upon adjustment) crossing an OR of 1 suggests that there is no evidence of an association between long-term OM related HL and educational achievement.

7.5.5.1.3 IQ

Table 7.5 Differences in mean IQ scores at age 15 between children with and without long-term OM related HL in ALSPAC, adjusted for sex, ethnicity, socioeconomic group, maternal education, social deprivation, parity and maternal smoking in pregnancy and at 7 years

Outcome	Unadjusted n	Unadjusted regression coefficient (SE)	95% CI	p value	R^2	Adjusted n	Adjusted regression coefficient (SE)	95% CI	p value	R^2
Verbal IQ	5,113	-4.10 (1.42)	-6.89, -1.32	0.004	0.0016	3,365	-4.72 (1.69)	-8.04, -1.40	0.005	0.1374
Performance IQ	5,108	-1.81 (1.04)	-3.85, 0.24	0.083	0.0006	3,361	-1.48 (1.28)	-4.00, 1.03	0.247	0.0611
Total IQ	5,107	-3.06 (1.07)	-5.15, -0.97	0.004	0.0016	3,360	-3.15 (1.27)	-5.64, -0.66	0.013	0.1439

Children with long-term OM related HL were found to score lower than children without long-term OM related HL in IQ tests at age 15 (Table 7.3). The greatest differences were seen for verbal IQ, followed by total IQ, with only a minimal difference for performance IQ. Regression analyses revealed evidence of an association between long-term OM related HL and verbal IQ and total IQ scores (Table 7.5). Children with long-term OM related HL between the ages of 7-15 years were found to score a mean of 4 points lower on verbal IQ tests than children without long-term OM related HL between these ages. Scores for total IQ for children with long-term OM related HL were a mean of 3 points lower, which indicates a small effect on performance IQ as well. Mean difference in verbal and total IQ scored increased slightly upon adjustment for confounding. The 95% confidence intervals for these two outcomes show that the population means for these two outcomes also show children with long-term OM related HL as scoring more poorly on IQ than children without long-term OM related HL.

7.6 Discussion

This chapter investigated the impact of long-term OM related HL experienced between 7 and 15 years on cognitive, educational and mental health outcomes at 10-11 and 15-16 years in ALSPAC. Evidence of an association between educational achievement at 15-16 years and anxiety and depression at 10 and 15 years was not found. Evidence of an association with IQ at age 15, however was presented, with children with long-term OM related HL scoring lower on verbal and total IQ. These findings suggest that while long-term OM related HL may influence cognition during adolescence, it does not have a negative influence on educational achievement or mental health.

Most of the limited literature conducted on the impact of OM related HL on psychosocial development and mental health in which increased levels of emotional symptoms and internalising behaviours in relation to anxiety and depression were reported, were case control and cross-

sectional studies (Timmerman et al., 2007; Gouma et al., 2011; Stenton, 2007). This larger, prospective longitudinal study, however presented that long-term OM related HL does not influence mental health.

Past studies looking at the impact of long-term OM related HL on academic ability as reviewed in Chapter 4 presented inconsistent evidence of an association. The outcome measures used in these studies were heterogenous, with associations with performance on standardised tests of achievement not being presented, however, associations with specific academic skills such as spelling, reading and verbal math skills were reported. The finding relating to academic achievement in ALSPAC presented in this chapter falls in line with that reported on academic achievement in Chapter 4. As this chapter did not look at individual skills, this cannot be reported on.

Although the IQ scores at age 15 in ALSPAC may be an underestimate of IQ, children with long-term OM related HL still scored lower than children without long-term OM related HL. The association presented with IQ at age 15 in ALSPAC provides supporting evidence for the associations reported in past studies by Hall et al., (2014) and Bennett et al., (2001) as reviewed in Chapter 4. Using longitudinal data from the Dunedin study, Bennett et al., also reported associations between long-term OM related HL and verbal and non-verbal IQ in adolescence at ages 11 and 13. The ALSPAC findings present this association with IQ in adolescence whilst also controlling for more sociodemographic factors than those of the Dunedin study.

Hall et al., (2014) also studied OM related HL and IQ in ALSPAC in earlier childhood. They reported associations between HL experienced between 8 months and 4 years and IQ at 4 years, but associations with IQ at 8 years were weak or not significant. Together with the findings from these analyses at later ages, it can be inferred that early HL that does not persist into later childhood, does not negatively influence cognitive ability over the long-term. This is reflective of sensitive periods of development occurring in childhood where changes in a child's development can occur. The findings from studies on the reversible effects of CHL on the central auditory system are also reflected here

(Moore, 1985; Moore et al., 1991; Moore et al., 1999; Hogan and Moore, 2003). However, as reflected in the finding from this later analysis, a long-term OM related HL in later childhood and adolescence does have a negative impact on cognition, suggesting that long-term OM related HL can potentially negatively impact a child's cognitive development if experienced beyond the early ages.

Furthermore, while Hall et al., (2014) reported associations with verbal, performance and total IQ at age 4, in this study, at age 15 associations were only found with verbal and total IQ. Although there was no association with performance IQ, the lower total IQ score at 15 suggests that performance IQ, although less than verbal IQ is still affected slightly in children with later long-term OM related HL. On a whole, the findings suggest that while children's non-verbal cognitive abilities may improve with time, their verbal cognitive abilities are still affected by long-term OM related HL. Nevertheless, whether this impact is long-lasting after the HL resolves is not known due to IQ not being assessed at another later time point.

Much of the theory presented in Chapter 2, portrayed that potential difficulties with the development of language and communication ability arising as a result of long-term OM related HL may potentially influence psychosocial functioning, which in turn may pose a risk to educational achievement given that much learning occurs through a social process within schools. Furthermore, the potential resulting effects on the quantity and quality of social relationships, may have also manifested through the child's mental health. The findings presented in this chapter, however revealed that mental health is not affected and children with long-term OM related HL do not perform more poorly than their peers on standardised tests of academic achievement.

Associations between long-term OM related HL and depression and anxiety were not found at any age in ALSPAC. It can be argued that these measures at age 10 were obtained via parental report and thus may have been underscored as parents would not accurately pinpoint how children were feeling. However, depressive symptoms at age 10 was measured through self-report and no association was uncovered. These findings are contradictory to those of the Millennium Cohort

Study (MCS) which found that late onset HL without resolution was associated with depressive symptoms at age 14 which was also measured using the SMFQ. Nonetheless, as the MCS studied HL of different types and degrees, associations may have been more likely to occur in children. Having said this, the limitation of the MCS using parent reported hearing data and self-reported data on perceived hearing difficulties at age 14, means that HL estimates may have been overestimated. It is important to note that the association between depressive symptoms was found with late onset HL which includes HL at 14 years. It has been reported that self-rating of poor health is associated with depressive symptoms, thus children with depressive symptoms in the MCS may have been more likely to have perceived themselves as having hearing difficulty (Rantanen et al., 2019). The use of standardised hearing measures in ALSPAC ensured that HL was reliably measured, and this was avoided.

Additionally, a key aspect to consider is that this thesis studied associations with actual psychiatric diagnoses assessed by the DAWBA as opposed to experience of emotional symptoms relating to anxiety and depression like other studies have presented in the literature. This may explain why only few children in ALSPAC were found to experience either generalised anxiety, social anxiety or depression. Interestingly, a higher number of children were found to experience depressive symptoms at age 10, as measured by the SMFQ. Scores on the SMFQ in ALSPAC were found to increase in adolescence and adulthood (Kwong, 2019). Had depressive symptoms been measured using the SMFQ at age 15, more children may have presented with symptoms compared to those who received a diagnosis of depression through the DAWBA. This may have also been true for anxiety, if general measures of symptoms were adopted. Nevertheless, although children and adolescents with long-term OM related HL may experience some emotional symptoms, these findings using validated measures of psychiatric diagnoses, represent that there are no major implications to their mental health.

Chapter 2 also suggested that through poor speech and language development resulting from the HL and with psychosocial functioning affecting learning, a child's cognitive ability may also be impacted by long-term OM related HL. This in turn, may impede on their educational achievement, with poorer ability and achievement potentially affecting their mental health. The findings in ALSPAC while revealing an association between long-term OM related HL and cognition, did not provide evidence of an association between either educational achievement or mental health.

This study measured educational achievement as passing 5 or more GCSEs and most children with long-term OM related HL (66%) were found to have achieved this. Although this finding implies that the poorer cognitive ability of children with long-term OM related HL does not impact their academic achievement, the outcome measure used in this study does not allow us the gauge the exact impact that this has on academic performance. Having information relating to the grade achieved for each subject would inform us whether children with long-term OM related HL are achieving poorer grades than their peers and allow us to see whether children are performing more poorly on literacy based subjects for example, which would be reflective of the poorer verbal IQ scores. Other studies have reported lower scores for academic skills in children with OM related HL loss when compared to children without HL (Roberts et al., 2000; Roberts et al., 2002; Bennett et al., 2001). Bennett et al. (2001) found that children scored lower for reading and spelling into the teen years. This current study, however, shows that poorer ability in these areas does not necessarily affect the overall achievement required to move onto higher study or work and does not leave these children at a disadvantage.

The educational achievement at KS2 and GCSE level of children with hearing and/or visual difficulties at age 7 in ALSPAC was studied by Hill et al. (2019). Although the impact of HL on KS2 SATs was not considered in this thesis, Hill et al. (2019) reported that children with either hearing or visual difficulties were less likely to achieve level 4 or above in their KS2 SATs, with a greater effect for English compared to Maths and Science. However, these associations were found to be attenuated

when analyses controlled for IQ and confounding factors. Furthermore, children with co-occurring hearing and visual difficulties, were even more less likely to achieve level 4 or above in KS2 SATs, even after adjustment for IQ and confounders. Similarly, at GCSE level, children with hearing difficulties were less likely to achieve 5 or more A*-C grades, however this association was attenuated after adjustment for IQ and KS2 achievement, suggesting that these factors mediated the association. These findings consolidate that OM related HL alone does not have a direct effect on meeting the national target grades for academic achievement. They also show however, that earlier academic achievement and IQ may contribute to later academic achievement in children with OM related HL.

The findings presented in this chapter inform us that while long-term OM related HL influences cognitive ability, children are not disadvantaged in their academic achievement and are not more likely to experience anxiety and depression. Having said this, as presented earlier in this chapter, social status is linked to both academic achievement and mental health. As ALSPAC participants were more socially advantaged than children from the rest of the population, the mechanisms through which long-term OM related HL may impact educational achievement and mental health may not have been as pronounced. For example, coming from families with higher social status may also mean receiving additional support from parents and other resources and thus a higher quality educational environment and quality of life, making it less likely for children to develop mental health issues. Whether this is valid cannot be ascertained however, particularly as the work by Hill et al. (2019) presented associations with academic achievement that were explained by IQ and other factors. Further work studying associations in other populations including children who are less advantaged is required.

The association with IQ and in particular verbal IQ, supplemented by findings from Hall et al. (2014) portrays that HL associated with long-term OM has long-term effects on cognition that do not

resolve if the HL persists. The impact is more strongly presented with verbal cognitive ability, demonstrating the persistent effects of the HL on the ability to process speech and language input.

7.6.1 Strengths & weaknesses

The main strength of this study is the use of repeated objective measures of hearing to classify OM related HL. While other longitudinal studies have attempted to study the effects of OM on child development, ALSPAC has the advantage of adopting repeated prospective measures of hearing though standardised assessment at each age for a large number of children. This has allowed the study of the impact of conductive HL associated with OM as opposed to studying the presence of middle ear effusion alone or parent reported or retrospective measures of hearing. In addition, the collection of data on various measures at different timepoints in ALSPAC allowed analyses to account for potential confounding effects. Having said this, a limitation of this study relates to the sample studied being more socially advantaged than the rest of the cohort. Children who attended the clinics were from higher socioeconomic backgrounds, as well as mostly being female. Furthermore, although the cohort was predominantly of White ethnicity, it was mainly those who were White who attended the clinics. As these differences relate to risk factors of OM and mental health and those linked with academic achievement, the findings of this study, thus may not be generalisable to children who differ in these characteristics.

Moreover, children enrolled in ALSPAC were found to have a higher educational attainment at 16 compared to children from the rest of Great Britain (Boyd et al., 2013). Therefore, the finding of no association between long-term OM related HL and educational achievement in this study may be subjected to selection bias as the grades achieved were higher in this cohort compared to the national population.

This relates to a further limitation of this study which is being subject to attrition bias. In this study analyses of associations were carried out on a complete case basis and did not include children who had missing outcome data. Methods of data imputation to account for missing data were not applied. The amount of missing data increased with time as fewer children attended clinics at each time point. As mentioned, children who were female and more socially advantaged were more likely to attend assessments compared to males and children from lower social backgrounds. Therefore, the characteristics of children lost to follow up also differed than those who provided data at all time points. The definition of long-term OM related HL in this study was dependent on attending two or more of the clinics. The difference in educational achievement between the ALSPAC sample and a sample of children from the rest of the nation, increased with increasing completeness of participation in ALSPAC. Additionally, children who had not recently participated or were lost to follow up were found to have a lower educational achievement than the national average (Boyd et al., 2013). This reduces the confidence that can be placed in the finding that long-term OM related HL does not have an impact on education. Furthermore, as a dichotomous variable, this measure of educational achievement may lack sensitivity and does not provide a more thorough view of the impact of long-term OM related HL on educational achievement due to a loss of information on each grade achieved for each subject.

Children in this sample were socially advantaged and high achievers. Hence, as lower social background and poorer educational outcomes are risk factors to mental health, this bias may have also influenced the mental health findings. Belonging to a higher social background also means having access to greater educational support e.g. support from educated parents and private tuition. With this extra support there is less for children to be worried or distressed about, hence it would have a positive effect on their mental health. Children in ALSPAC with long-term OM related HL were found to have lower IQ than children without long-term HL. Differences not being presented with the other outcomes may reflect environmental advantages. Further research is required to study outcomes in less advantaged children.

Furthermore, in relation to the mental health findings, measures at 15 years were taken during the focus clinic assessment which required attendance rather than filling in a questionnaire. As anxiety involves worrying about situations, those with anxiety may have been more likely to not attend focus clinics, particularly those with social anxiety who may not have attended due to avoidance of social interaction (Brook and Schmidt, 2008). The same can be said about children and adolescents with depression who may have been experiencing low mood and loss of interest in partaking in the study.

Having said all this, this study is one of the few that has addressed long-term OM related HL and that being at later ages than typically studied. The ages studied ranged from childhood into adolescence which offers a life course perspective. The findings demonstrate cognitive ability being influenced by HL in adolescence. Although hearing data was not available at earlier ages to compare long-term OM related HL from early childhood across the life course, findings from other earlier work provide evidence of the effects of early OM related HL subsiding with time once HL has resolved. This study provides a basis for further exploration of the impact of long-term OM related HL across the life course.

7.7 Chapter summary

This chapter investigated the impact of long-term OM related HL on cognition and educational and mental health outcomes in ALSPAC across childhood and into adolescence. Long-term OM related HL was found to be negatively associated with IQ scores at 15 years. No association was found with educational achievement at 15/16 years and mental health at both 10 and 15 years. These findings suggest that the lower cognitive ability and implications that long-term OM related HL may have to psychosocial development do not lead to children underachieving at school or developing mental health issues at a population level.

As existing qualitative research has identified that children with long-term OME related HL do experience implications to their psychosocial functioning and educational experiences, the mechanisms by which children's educational experiences and social and emotional functioning are influenced by this HL at an individual level must be studied more closely. The next chapter introduces research that has been designed to do this.

Chapter 8. Next stage: A qualitative exploration of the impact of long-term OME and related HL on children and adolescents and their information and support needs

8.1 Background

The research presented in this thesis revealed associations between long-term OM related HL and IQ at 15 years. However, associations between long-term OM related HL and academic achievement and mental health were not presented. Although it is encouraging to see that academic achievement and mental health are not affected by long-term OM related HL, previous qualitative studies have reported that children's educational experiences were impacted by the psychosocial implications of their HL. Therefore, while academic grades may not be greatly affected, it may be the school learning experience itself that presents with difficulties to children with long-term OM related HL.

The quality of school experiences is important for peer relationships and learning as schools provide an environment in which learning takes place through interaction with peers as well as teachers at school (Vygotsky et al., 1962; Nyandara et al., 2018). Thus, assessing children's school experiences may tell us more about how their HL affects them through their communicative behaviour, than assessing achievement outcomes such as their school grades. While grades are used to determine how much and how well students have learnt the taught information, preparation for these assessments can occur outside of school e.g. through individual study/revision or extra tuition. Hence, school grades do not give us the full picture on how long-term OM related HL affects education and learning at school. Therefore, a more detailed account of the school experience is required.

Research taking a qualitative approach was designed to explore how long-term OME related HL influences social interactions for children and adolescents at school and how it influences their career path. As it has already been identified to an extent that children with OME related HL experience problems with their educational experiences, the basis of this research was to explore this further to gain a deeper understanding of the ways in which these occur; as well as to explore how these children can be better supported. As part of a study exploring the support needs of children, the research was designed to take the approach of exploring their support needs generally as well as that from an educational perspective, particularly as guidance for the management of long-term OME related HL is lacking. Therefore, as well as obtaining data from children and adolescents living with the condition, the research was designed to obtain data from parents and clinicians as well as from young people in early adulthood who have experienced long-term OME related HL during school age and would be able to reflect on their experiences and how these influenced their career and life choices. Obtaining data from clinicians (i.e. Audiologists and ENT consultants) would also provide a clinical perspective.

This research was designed to be split into two linked studies, one which would focus on exploring social interactive behaviour at school and career choices and one focusing on exploring the information and support needs of children and their families.

A protocol for this research taking the form of two related studies was developed and submitted for ethical review in October 2019. The research received NHS HRA ethical approval in January 2020 with participant recruitment due to start in March 2020. However, with the ongoing national lockdowns due to COVID-19, issues with NHS services being unable to assist with recruitment of participants at this time, closure of schools which were pertinent to this research and the uncertainty of this for the foreseeable future, along with other circumstantial issues, the research could not be carried out. This chapter details this planned research, much of which has been taken from the research protocol which can be found in Appendix D.

8.2 Research objectives

8.2.1 Study one

8.2.1.1 Aim

The aim of this study was to explore the social interactions of children and adolescents with long-term OME related HL and the influence this may have on their educational progress and career path.

8.2.1.2 Objectives

1. To observe and describe the social interactions of children and adolescents with long-term OME related HL in a school environment
2. To explore past and present experiences of social interactions of adolescents with long-term OME related HL.
3. To understand the emotions that children and adolescents with long-term OME related HL feel when interacting or anticipating interaction with others.
4. To explore how the social behaviour of children and adolescents with long-term OME related HL at school influences their learning
5. To explore the career choices of adolescents with long-term OME related HL

8.2.2 Study two

8.2.2.1 Aim

The aim of this study was to explore the information and support needs of families and children with long-term OME and related HL in managing living with the condition.

8.2.2.2 Objectives

1. To explore how families and children with long-term OME related HL are supported by services such as the NHS and educational services from the perspectives of parents, clinicians, and affected young people.
2. To explore the information needs and support required by families and children with long-term OME related HL from the perspectives of parents, clinicians, and affected young people.

8.3 Approach and framework

Both studies were designed to take an interpretivist approach which relates to discovering knowledge about the world through the social world in which we live in and would utilise constructivist grounded theory methodology (Braun and Clarke, 2014; Urquhart, 2013; Charmaz, 2006). Schools make up a big part of children's and adolescents' social world and their experiences can influence their knowledge and experience of the world at later stages, so exploring this social

world at school can give insight into the development and lives of children and young people with long-term OME related HL (Epps and Smith, 1984; Ladd, 2005). Constructivism acknowledges that reality is constructed by those who experience it and using grounded theory methodology within this approach would allow the researcher to construct an interpretation of participants' lives, living with long-term OME and HL (Birks, 2014).

Grounded theory (GT) methodology is suitable where there are models available to explain a certain phenomenon but not for the population of interest to the researcher (Creswell, 2007). While it is known that the development of children with permanent HL is impacted with intervention and support for these children in place, here GT would be used to uncover any impact that long-term OME related HL may have, as well as to put in place a framework of the families and children's support needs. Using this approach would help to access areas that cannot be done with quantitative research, by communicating with those affected and those involved and collecting data from the lives and contexts of the participants (Gordon-Finlayson, 2010).

This research was designed to particularly explore the social interactive behaviour of children and adolescents with long-term OME and related HL. Exploring their interactive behaviour at school would help to explore the impact on learning and academic success by identifying factors which may be influencing their learning and school experience. Naturalistic data would be obtained through observation in order to describe the social interactive behaviour with teachers and peers and engagement at school. Teachers of the children/adolescents would also be interviewed to obtain data that would inform how social behaviour and engagement in the classroom may influence their learning. From this the researcher may identify ways in which schools and teachers could improve the experience for children with HL. Interviewing the children's teachers would also aid in understanding the knowledge of teachers on OME related HL, as well as the child's performance in class over the academic period and where they feel support is needed for children with long-term OME related HL. Furthermore, to gain a perspective on how the condition may affect adolescents at

a later stage in life, young people would be interviewed to tell us about their social behaviour at present. They would also reflect on their past interactive behaviour at school and the emotions associated with this, and how this all may have influenced their career path and aspirations. Having young people reflect back on their earlier experiences as well as providing information on their life at present would provide a view of how they have or have not been affected across their lives.

The findings from the first study described above were anticipated to also inform the second study which would focus solely on the information and support needs of children with long-term OME and related HL. Views would be obtained from a range of people including young people with or with a history of the condition, parents of children and young people with the condition, clinicians, and the teachers from the first study. Past qualitative studies conducted in Canada have highlighted that the family is important when considering how to manage living with OME and have identified that the family's relationship with the healthcare system is key (Wuest and Stern, 1990; Wuest, 1991). Hence, it is important that both parents and clinicians were involved in this study to obtain their views and see if this is reflected. An exploration of these views may lead to an insight into how families and children with long-term OME and related HL can be better supported.

8.4 Participant recruitment

This section details the recruitment procedures that would have been adopted by this research. It was planned that the research would take place in Birmingham or surrounding areas within the West Midlands as this is where the research team were based. Accordingly, children, young people, parents and teachers would have been recruited from within Birmingham and clinicians would have been recruited from across the West Midlands.

8.4.1 Children, young people and parents

The main method of recruitment planned for these participants was through NHS Audiology and ENT departments within Birmingham. The Audiology and ENT departments at Birmingham Children's Hospital (BCH) and University Hospitals Birmingham (UHB) Trust were on board to support recruitment of participants for this research.

Recruitment routes for children, young people and parents through the NHS involved identification through patient databases, identification of eligible participants in audiology and ENT clinics and study advertisement in ENT and audiology waiting rooms. Non-NHS recruitment would have occurred through local charities such as the National Deaf Children's Society Birmingham district.

8.4.2 Identifying schools and teachers

It was planned that the schools/colleges of 7-18-year olds who would have consented to take part in Study 1 would have been contacted by the researcher. The researcher was to contact the Head Teacher informing them of the study and that their student had agreed to participate in the study, asking for permission to conduct the research at their school. The Head Teacher would have also been informed that the researcher would like to interview at least two of the student's teachers outside the school day. Thus, the study information would be sent to the child's teachers who would contact the researcher if interested in taking part in the study.

8.4.3 Clinicians

Clinicians for Study 2 were to be recruited through the Birmingham Children's Hospital (BCH) and University Hospitals Birmingham (UHB) Paediatric Audiology departments. It was arranged for the Head of Audiology at BCH and Paediatric Clinical lead at UHB to distribute the invitation and participant information sheets to their Audiology and ENT colleagues within their department and across the West Midlands.

8.4.4 Incentives and reimbursements

Children, young people, and parent participants were to be offered a £10 shopping voucher as a thank you for them taking part in the research. Expenses for travel to Aston University were also to be reimbursed for all participants.

Further detail on recruitment procedures as well as specific detail on eligibility criteria and all participant information sheets and posters can be found attached to the protocol in Appendix D.

The next section outlines the methods of data collection and analysis for each study.

8.5 Study one

8.5.1 Methods of data collection

This study was designed to utilise observations and semi-structured interviews to collect data which would be triangulated. The use of these methods is described in more detail below.

8.5.1.1 Observations of children/adolescents at school/college

To gain an initial view of the social interactions of children with long-term OME and related HL at school, ethnographic observations would allow description of the phenomenon and enable the researcher to build a substantial grounded theory by describing and interpreting their observations within the school culture, which is where most children within the UK spend most of their time (Streubert and Carpenter, 1999). Ethnography is a qualitative research design in itself in which the researcher describes and interprets the shared and learned patterns of values, behaviours, beliefs and language of a culture-sharing group (Harris, 1968). Through this participant observation, the researcher would be immersing themselves in the day to day lives of children while they are at school. While each child who was to be observed in this study would not be grouped with the other children with long-term OME related HL while being observed, from the individual accounts of data the researcher would be describing what the school culture is like for a group of children with long-term OME related HL.

The target population for these observations were 7-18-year olds with long-term OME and related HL or a history of long-term OME and related HL who would have been observed by the researcher at their school both in and out of class over a period of 2-3 days. This is so that the child would be observed during different time points of the week as well as during different lessons. Interactions would be observed while the child was in lesson and any after school activities that they took part in. This would have provided observation of the child in both an educational and a more social perspective.

It was planned that the researcher would liaise with the school after recruiting the participant to ensure that the participant would be observed in English and Math's lessons as these are core subjects, as well as subjects that the participant enjoyed the most and enjoyed the least. This was to be able to describe how engagement and interaction in class may differ with levels of motivation as motivation is understood to be a pre-requisite of and a necessary factor for student engagement in learning (Saeed and Zyngier, 2012). The participant would be asked beforehand when discussing study details and obtaining assent/consent, which were their most and least favourite subjects.

During observations the researcher would be taking field notes which would include notes on interactive behaviour, the nature of the interactions, class participation, body language and facial expressions. They would also be looking out for any hearing difficulties that the child may have e.g. mishearing information and take note of these and what follows. Close following of the participants body language and facial expressions would allow the researcher to pick up on information that may otherwise not be apparent e.g. confusion or signs of anxiety when being asked to contribute to discussions.

The participant would have also been observed outside of the classroom, for example, during after school clubs/activities that they were involved in. This would allow observations to be made of interactions in a more social context during which participants may or may not be more engaged than during class. The researcher would focus on whether the participant interacts with others during this time or keeps their own company.

Once observations were completed, they would be written up fully by the researcher, ready for analysis. Although the participant would be observed while amongst others, data would not be collected on any other child other than the participant as this would raise ethical issues. The approved protocol states this clearly. An observation guide is presented with the protocol.

8.5.1.2 Interviews with teachers

Obtaining interview data would aid not only in describing the phenomena, but also in understanding the impact that long-term OME related HL may have on social interaction and emotional behaviour (Aldiabat and Le Navenec, 2011; Chenitz and Swanson, 1986; Glaser and Strauss, 1967; Hutchinson, 1986).

Interviews with the teachers of the participants who would have been observed were planned to take place after observations. The data from these interviews were anticipated to gain further insight into the child's interaction in class throughout the time that the teacher had been teaching them, and their progress in class. The interviews would have further informed the researcher's observations. Teachers would have also been asked questions regarding their views on the support needs of families and children with long-term OME related HL to feed into Study 2.

These interviews were to be semi-structured involving mainly open-ended questions and occur face to face at the end of the school day after the child had been observed, lasting around 15-30 minutes. The standard interview schedule is presented in the protocol.

8.5.1.3 Interviews with older adolescents

The research would have also involved interviews with young people (18-24-year olds) with long-term OME related HL who were no longer in school. This target population of young people may already have been working or in further education, so it was planned that interview questions would cover their social interactive behaviour in the past but also at present, including but not limiting this to their behaviour at school to see how they go about interaction within society in general now that they are older, as school is also deemed important for societal functioning (Epps and Smith, 1984).

As these participants would have been older, the researcher would have also asked questions based on how they got to where they are today.

These interviews were also planned to be semi-structured and occur face to face. Participants would be asked questions pertaining to their current and past interactions/relations to obtain data which covers a longer period from childhood up until now to tap into impact over the life course. Questions regarding their interactions and associated emotions would also be asked to try to identify why participants may or may not interact in a certain way. These questions would be pertinent to obtain data that would allow an understanding of the emotional/internalising symptoms that children and young people with long-term OME related HL may feel and the extent of the implications. Questions thus would mainly have been open ended to obtain this detail. As expressing emotions is a sensitive process, participants would have been given the options of responding verbally or using drawing as a way to help express their responses if they wish to, e.g. drawing figures or mind maps. If the participant was not comfortable with either verbally answering or drawing, they would also be able to write down their responses.

As well as this, participants would also have been asked about their educational attainment throughout life and how content they felt with this as well as their career aspirations. These questions would be asked to gain an insight into whether children with long-term OME related HL are impacted beyond childhood and throughout life and in order to get a view of how their beliefs about their communication behaviour and educational attainment may influence their career decisions and life goals. This would further highlight the support needs of these individuals. Interviews were anticipated to last between 30 and 60 minutes and the general interview schedule to be used is presented in the protocol.

All interviews would have been audio-recorded using an encrypted Dictaphone and the researcher would have taken field notes during the interviews, noting facial expressions/body language etc. that cannot be picked up by audio.

8.5.2 Sampling

8.5.2.1 Size of sample

The aim was to recruit 20-30 individuals in total to take part in this study in line with the suggested sample size required to develop a well-saturated theory (Creswell, 2007). It was anticipated that there would be more participants for observations than for interviews, therefore it was expected that around 10-15 children and adolescents for observations would be recruited and 10-15 teachers and 5-10 young people would be interviewed.

8.5.2.2 Sampling technique

Purposive sampling would initially have been used to recruit participants for this study. Participants who were NHS Audiology/ENT patients within Birmingham who were eligible and could contribute to the development of the theory would have been recruited (Creswell, 2007). Once data collection had begun and theory ideas had started to emerge, theoretical sampling may have also been used to recruit individuals who could contribute to the processes of coding used in grounded theory analysis procedures and add data to the already identified categories (Strauss & Corbin, 1990). The process of constant comparison would allow the researcher to have identified the type of participant needed to add to developing theoretical ideas (Creswell, 2007).

8.5.3 Methods of data analysis

The main mode of analysis for this study would have been grounded theory methods. GT involves data being analysed in parallel with data collection, rather than all data being collected and analysed at the end of data collection (Creswell, 2007). This allows the process of constant comparison where information obtained from each set of data is compared to that which has been analysed previously and allows emerging themes to be compared to currently identified themes. This analysis process also allows theoretical sampling to occur, where the selection of participants for the next set of data collection is informed by the themes that have already emerged (Creswell, 2007).

Analysis would have begun from the first point of data collection where the complete field notes for the observations were descriptively written up by the researcher, from which key themes were to be sought out as is done in ethnographic analysis (Creswell, 2007). The themes from the observations and the transcribed data and field notes from the interviews were to be analysed using GT methods of analysis. The combination of observational themes and interview data would be analysed through constant comparison where information would be compared to emerging categories (Strauss and Corbin, 1990).

The interview data were to be coded first through the process of open coding to generate categories of information that are supported by the text (data) (Strauss and Corbin, 1990). The observational data were then to be brought together with the interview data from both the older adolescents and teachers, where the themes and codes would undergo axial coding to identify a central phenomenon. Data collection would continue to identify further categories relating to this central phenomenon which would be identified from a category that is commonly discussed by participants or one of specific interest as seeming central to the phenomenon being studied. This information would then be organised into a coding paradigm that presented a theoretical model of the impact of

long-term OME related HL on children and young people. Selective coding would then be used to integrate and refine the categories which would build a story by connecting the categories. These analysis procedures would be used to develop a theory from each study, grounded in the data collected from participants.

Throughout analysis, the researcher would write *memos* – ideas about the emerging theory. This constant comparative process of analysis would feed into subsequent sampling based on the data already collected and would inform further questions to be asked during interview, allowing the testing of emerging ideas until data saturation.

8.6 Study two

8.6.1 Methods of data collection

As there is no set support framework for this group of children, the resulting theory developed from a range of participants' experiences may be used to provide a framework for practice (Gordon-Finlayson, 2010). This was planned to be achieved by having focus group discussions or interviews with young people with long-term OME and related HL (13-24 year olds), as well as with parents and clinicians of children/young people with long-term OME and related HL, to derive a theory from a range of experiences of people who may be involved in supporting these children. Interview data from teachers from Study 1 would also add to this data.

8.6.1.1 Focus groups

It was planned that focus group discussions and interviews would be facilitated using Pictor, a visual research technique designed to explore the experiences of collaborative working in health and social care contexts (King et al., 2013). The technique involves participants using arrow-shaped adhesive notes or cards to build a representation of the roles and relationships in a particular case. The chart that is produced aids the participant in sharing their experience and elicits further exploration. It was anticipated that the charts produced by participants would give a representation of where they feel the support for families and children with long-term OME and related HL is needed. Each focus group discussion was expected to last approximately 60 to 90 minutes.

8.6.1.2 Interviews

Where interviews were to take place, these would follow the same structure with the participant first creating a Pictor chart and then discussing this with the researcher. The constant comparatively analysed data from the initial focus group and prior interviews would inform the structure of each interview and further questions to be asked, but this would be the general structure. Interviews were expected to last approximately 30-45 minutes. The initial topic guide for focus group discussions and interviews is presented in the protocol in Appendix D.

Discussions and interviews were to be audio-taped using an encrypted Dictaphone. The researcher would take field/scratch notes during discussions/interviews to aid analysis. Full field notes would then be written up after the focus group discussion/interview had finished. The data to be analysed would comprise of the Pictor charts, the recorded data and field notes.

8.6.2 Sampling

8.6.2.1 Size of sample

The aim was to also recruit 25-30 participants in total for this study. It was anticipated that within Birmingham alone, there may have been a modest number of young people with long-term OME and related HL, hence, it was expected that 10-15 young people and parents would be recruited. In regard to clinicians, there are three hospital trusts within Birmingham itself from which clinicians would have been recruited. As clinician recruitment was also open to the rest of the West Midlands, it was expected that at least 10-20 clinicians would be recruited.

8.6.2.2 Sampling technique

This study would have also utilised purposive sampling where the researcher chooses participants who can contribute to the development of the theory (Strauss and Corbin, 1990). The findings of the initial focus group would be used to guide recruitment of participants for the next focus group/interview and so on via theoretical sampling to aid the process of thematic development (Strauss and Corbin, 1990). It was anticipated that the analysis process would inform the particular characteristics of the next set of participants that would need to be recruited through theoretical sampling but also if the analysis process indicated that information is needed from other groups then these individuals will be sought to participate in this study. If more numbers of participants were required then they would be recruited, if time permitted.

8.6.3 Methods of data analysis

As described with the first study, analysis using GT methods would have begun from the first point of data collection through constant comparison. While scratch notes would be taken during discussions, analysis of Pictor charts, field notes and audio recordings would begin as soon as possible through open coding where the data would undergo initial categorisation. The remaining coding procedures would be carried out as data were continually collected with the researcher writing memos, to develop a theory grounded in participant data surrounding the support needs of families and children with long-term OME related HL.

The analysis procedures would help to inform the participants needed to be recruited as well as the structure of discussion for the following groups/interviews.

8.7 Ethical and practical concerns

Potential concerns with this research were addressed in the protocol, which was reviewed and approved by the NHS West Midlands Edgbaston research ethics committee (reference number: 19/WM/0337).

This section briefly outlines these concerns.

8.7.1 Consent

A key ethical issue with this research was that of consent, particularly as this research involves children. Informed consent/assent was to be obtained from all participants. Before obtaining consent/assent, it would have been ensured that potential participants had full awareness of the

purpose of the project, the procedures, analysis, data storage and potential outputs and will have had the opportunity to ask questions. They would be made aware that:

- Anonymity would be protected through assigning aliases and patient identification numbers
- Confidentiality would be maintained throughout by the researcher, with the exception of the unlikely situation where the researcher may find themselves in a *duty of care* position
- Although all participants would sign a confidentiality agreement, confidentiality on behalf of the other participants in focus groups could not be guaranteed.

In general, while informed written consent was to be obtained from participants aged 16 years and above, verbal assent was to be obtained from participants aged under 16 years, with informed written consent from their parents/guardians. For the study utilising observational methods, consent/assent would not have been obtained from the participant's classmates and classmate's parents as the researcher would only have been interested in observing the participant and would only be collecting data on them and not on their peers.

8.7.2 Participant safety

Risks to the participants associated with this research would have been limited with the observational and interview methods being used. However, the actual burden of being observed for children would be present. To ensure that the participant did not feel as though it was solely them being observed, the researcher would have sought to be as naturalistic as can be. Participants were to be observed whilst being amongst others and the researcher would keep their distance where possible to not influence the participant's behaviour.

A burden that may have been present for young people being interviewed or taking part in focus groups was any psychological distress resulting from discussion of sensitive topics such as emotions, socialisation and educational attainment or managing to live with long-term OME related HL. To limit any occurrence of distress, the researcher would have ensured that the participant was willing to address these questions prior to starting the interview/discussion. If the participant was happy to continue, the researcher would be cautious, keeping any signs out for discomfort or distress. The participant would be told that they could withdraw from the study at any point if they wished. The researcher would identify any participants with particular distress (and notify parents/guardians for participants 13-18 years old) and suggest onward referral if necessary, according to local protocols.

13-15-year olds would have needed to be accompanied to the focus group or interview by their parent/guardian. If interviews were to be conducted in the participant home, parents would be required to be home at time of interview. Parents could either be present in the same room during interview or not, depending on participant preference. Where focus groups/interviews were to be conducted at Aston University, parents would have had to accompany their child to the site. Risk assessment of the setting where focus groups/interviews would be taking place at Aston University would have been carried out beforehand by the researcher.

Participants may not have been comfortable discussing issues with strangers in focus groups, particularly the young people and parents as this would be personal to them. However, they would be introduced to each other and made aware that they all shared the common experience of living with long-term OME and related HL. Parents attending the focus groups with their child would also be asked to keep discussions confidential.

Any issues revealed during the study regarding participants and safeguarding would be reported to the relevant parties according to local protocols. Issues which may have been raised during school observations would be reported to the school Head Teacher.

All participant data would have been anonymised and kept confidential unless it needed to be disclosed if participant safety was threatened. As participants would have been interacting with others during focus group discussions, all participants would have been asked to sign a confidentiality agreement. Participants would have been given the right to withdraw at any point during the study.

8.7.3 Researcher safety

Risks to the researcher may have been present in the case of lone working where interviews would take place in participants homes. The researcher would abide by the Aston University Lone working policy and ensure that they have frequent contact with the other members of the research team by phone who would know where they were at all times. Where possible, the researcher would have been accompanied by another researcher to reduce the risk of lone working.

8.8 Reflection

This research was designed to supplement the work presented in this thesis. However, by the time ethical approval was received, lockdown and social distancing measures in the UK due to COVID-19 had been put in place. This affected research plans firstly, as NHS Trusts had put a pause in their involvement in non-COVID related research which meant that recruitment of participants could not take place until this was lifted. Recruitment through non-NHS routes would not have been sufficient. Furthermore, the time restraints and increased workloads of NHS clinicians meant that this was not an ideal time for them to take part in the research.

In addition to this, research plans were affected as schools had closed which meant that observations of children and adolescents with long-term OME related HL in their school

environment could not take place. It was uncertain when schools would open as normal, thus even when the NHS was open to non-COVID research, this crucial part of the research could not commence. It was also uncertain whether these observations would be able to take place in the near future due to the effect of the pandemic on schools.

Contingency plans were attempted, and different methods of data collection were considered. However, it was anticipated that there would be issues with using remote and virtual methods with children in this context. Additionally, these changes meant that the work was not consistent with the overall research theme. With these challenges and setbacks, the most suitable option was to leave the research as planned which is ready and approved to be conducted, hopefully in the future.

8.9 Chapter summary

This chapter put forward a research approach to further explore the impact of long-term OME related HL and address the support needs of children and their families. This is an approach that was designed to explore social interactive behaviour of children and adolescents with long-term OME related HL within the context of education to identify which aspects of the educational experience are impacted, but also more generally to identify how children can be better supported. Findings from this work were to be integrated with the quantitative findings presented in this thesis to provide insight into the impact of long-term OME related HL and support needs of children with this HL. Future research may benefit from considering the aims of this research and planned procedures presented in this chapter.

Chapter 9. Discussion

This thesis set out to investigate the prevalence of long-term OM related HL and its impact on cognition, academic achievement and mental health. This was done using data from a prospective longitudinal population study and was informed by a systematic review of the current literature looking at the influence of long-term OME and related HL on cognitive and academic outcomes. This chapter reviews key findings and the strengths and limitations of the work undertaken while also addressing the implications of these findings and what this adds to our current knowledge.

9.1 Key findings

Epidemiological data on long-term OME related HL, particularly after the age of 7 years is sparse, where studies have reported on prevalence falling between 3-8% by 7 years (Simpson et al., 2007). One of the main aims of this thesis was to estimate the prevalence of long-term OM related HL in the population and this was done by analysing data from a prospective longitudinal birth cohort study - ALSPAC. Long-term OM related HL between the ages of 7-15 years was found to have a prevalence of 2.69% in ALSPAC. This infers that almost 3% of children experience persistent or recurrent OM related HL after the age of 7 years. This finding shows that while prevalence falls by 7 years, some children experience on-going HL related to OM.

Studies on childhood HL typically report prevalence rates for permanent HL through cross-sectional estimates. Analysis of the hearing data in ALSPAC in this thesis has contributed novel information in regard to childhood HL but also of a form of childhood HL that is not typically considered when

providing childhood HL estimates. Much focus is placed on children with permanent childhood hearing impairment, usually identified through new-born hearing screening, however the findings in this thesis portray that a greater number of children experience a long-term conductive HL which may extend from childhood into adolescence. These children do not experience the typical temporary OM related HL suggesting that more focus should be placed on these children to provide appropriate intervention and support.

While CHL at each individual time point was not found to remain steady across time with the prevalence decreasing with age in the ALSPAC cohort, the HL trajectories of children with long-term OM related HL revealed that this was not a consistent trend in the long-term CHL exposure as the long-term HL was revealed to have a persistent or recurrent nature. There was a mix of children experiencing HL early on, at the later ages, in between and at time points that were not consecutive. The occurrence of long-term OM related HL in children at 11 & 15 years, but not at 7 & 9 years was interesting to see with OM being known to be less prevalent beyond the age of 7. This finding shows that the likelihood of experiencing OM at later ages should not be underestimated.

On a whole, these findings demonstrate that some children experience long-term OM related HL into the teen years. Although it may seem as though long-term OM related HL has a low prevalence, this prevalence is higher than that of permanent childhood hearing impairment. This suggests that more surveillance is required for children who present with OM related HL as they may be part of the 2-3% who experience persistent or recurrent OM related HL.

This thesis also investigated the impact that long-term OM related HL may have on children and revealed an association with IQ. Findings from the systematic review revealed that IQ was affected at various ages throughout childhood and adolescence by long-term OME related HL at different points in childhood (Bennett et al., 2001; Hall et al., 2014). This systematic review was the first to focus only on studies which had studied OME related HL as the exposure as opposed to OME, allowing conclusions to be based on the impact of HL associated with OME. It was also the first to

ensure that repeated measures of hearing were undertaken by the selected studies in order to ensure that transient OME related HL was not being studied. Studying the cumulative exposure over a number of years allowed comparison between children who had shorter forms of OME and children with long-term OME related HL.

The findings from the analyses of long-term OM related HL between the ages of 7 and 15 years in ALSPAC also showed an effect on IQ during the teen years. This is interesting as Hall et al (2014) did not find a significant association between long-term OME and HL experienced between 8 months and 4 years and IQ at 8 years in a sample of children who were also part of the ALSPAC cohort. This finding provides support for sensitive periods of development occurring in early childhood, and children not having any lasting effects on development upon resolution of CHL as discussed in chapters 2 and 4, particularly as Hall et al. (2014) reported significant associations with IQ at 4 years. In this thesis, long-term OM related HL in later childhood was studied, and the negative associations found with verbal and total IQ at age 15 suggest that later long-term OM related HL is associated with poorer cognitive ability in adolescence when compared to children without OM related HL at ages 7-15. These findings indicate that children with long-term OM related HL are at a disadvantage in terms of the development of their cognitive abilities over time. Having said this, as mentioned in chapter 2, some researchers believe that intelligence is fixed early in life around the ages of 5-10 years (Bjorklund, 1999). If this is the case, we cannot be certain whether it is long-term OM related HL between 7 and 15 years that leads to poorer IQ at 15 years or whether it is earlier long-term OM related HL that occurs earlier.

The systematic review revealed a similar trend as IQ for academic measures; however, the evidence was not as robust, thereby requiring further work to come to conclusions regarding the influence of long-term OME related HL on academic ability. Analysis of the ALSPAC data as part of this thesis did not present an association between long-term OM related HL and academic achievement. The difference in cognitive ability of children with and without long-term OM related HL in ALSPAC was

not reflected in the achievement of 5 or more A*- C GCSE grades, suggesting that the HL does not hinder academic performance. Nevertheless, this outcome did not measure the level of grade achieved for each subject to reflect ability in each subject and whether children with long-term OM related HL achieved fewer A* and A grades compared to B and C grades, which is where the differences in IQ may have been seen. Having said this, sitting an academic achievement test comes with more preparation for the test, hence children may overcome any difficulties through this extra preparation. Better educational environments and support may have been provided for children in the sample as they were children of more educated mothers, hence allowing them to perform better.

The literature infers that the risk of psychosocial issues does not differ with degree of HL, thus it is interesting to see that children with long-term OM related HL in ALSPAC did not exhibit anxiety and depression at a greater level than children without HL, particularly during the teen years. The DAWBA, used to assess for these outcomes predicts diagnoses of these conditions based on diagnostic criteria. Perhaps, an outcome which measured depressive or anxious symptoms at 15 such as the SMFQ or a measure of general emotional symptoms, as opposed to a diagnostic measure may have revealed associations. Furthermore, onset of mental health disorders increases with age with three quarters of mental health issues beginning by the mid-20s (Kessler et al., 2007). This is more likely for individuals who develop these as secondary conditions. While scores for depressive symptoms continued to remain low across time in ALSPAC, they were seen to continue rising from the age of 15 to the age of 19, after which they continued to rise from the age of 23 (Kwong, 2019). The onset of mental health issues in ALSPAC was seen to be later overall. Nevertheless, it is encouraging that analyses revealed that long-term OM related HL is not associated with mental health issues in later childhood and adolescence and further up to date work with other populations is required to make firmer conclusions.

9.2 Strengths & limitations

The greatest strength of the work presented in this thesis is using data from a large longitudinal birth cohort study. ALSPAC is the largest cohort study in the world to have obtained repeated hearing measures using standardised objective hearing assessments. Previous studies have obtained hearing data through parental/self-report or linkage to medical records and those which have used standardised measures of hearing had done so with a much smaller sample or had obtained measures at only one or two time points. The repeated measures in ALSPAC across four time points allowed the capture of HL which may fluctuate, which is characteristic of OM, and the longitudinal study design allowed analysis of OM related HL, whether this was persistent or recurrent or late onset. These analyses, being specific to OM related HL studied HL for a group of children whose HL may be overlooked due to its non-permanent nature. Furthermore, the focus of most research is on HL in early childhood as the importance of early identification and intervention is established, thus a strength of this research is providing needed data on HL in later childhood and adolescence.

The systematic review was the first to focus on the most robust prospective studies in the literature on the impact of OME ensuring that all studies accounted for OME related HL, with measures overtime to identify HL of a persistent nature. This has distinguished the higher quality studies which have focused on HL from studies which have not sought to specifically study the impact of HL as opposed to just MEE alone. Adding to this, ALSPAC also collected data on a range of variables which allowed analyses to control for relevant confounders that were not controlled for in previous studies. Controlling for confounding allowed comparison of findings to refute or confirm what was already presented in the literature.

Furthermore, this work has revealed a need for qualitative research to further explain children's experiences and help to drive patient centred care and support.

Having said this, all the work presented in this thesis is not without limitations. These include the ALSPAC data being subject to selection bias. Not only was the majority of the ALSPAC cohort from a White ethnic background but analyses also found that children who belonged to higher socioeconomic groups, had more educated mothers, lived in the least deprived areas and were female and White were most likely to attend the hearing assessments. While the ALSPAC cohort was concluded to be similar to the rest of Great Britain, the sample of children selected for the analyses in this thesis had to have attended two or more hearing assessments at the focus clinics, thereby indicating that the selected sample was biased in the direction of representing more advantaged children. These socioeconomic factors are strongly associated with academic achievement and mental health; therefore, findings may not be representative of children from lower socioeconomic backgrounds. Furthermore, as it was reported that children in the ALSPAC cohort were found to on average score higher in the educational attainment tests than the general population (Boyd et al., 2013), findings may not be representative of the greater population.

As a large longitudinal study which has collected data on various measures, ALSPAC is affected by attrition bias. A further limitation is that these analyses were run on a complete case basis and imputation of missing data was not carried out which may have addressed the selection bias occurring through attrition. What's more, secondary data analysis limited the selection of outcomes to be studied. While it was initially planned that outcome variables would be selected to represent a measure at an earlier time point and a measure at a later time point for all outcomes, for IQ, the earlier measured variable preceded the exposure and the limited KS2 SAT data available for the whole cohort led to a small sample for earlier academic outcome analysis, which had reduced power to detect an effect. Therefore, only mental health outcomes were studied at more than one time point. Another weakness, despite using data from a longitudinal birth cohort study, is that hearing data was not available from birth or early childhood in order to ascertain whether children with long-term OM related HL also experienced HL in early childhood. This would have further shed light on the recurrent nature of OM related HL and clarity around the continuation or resolution of late

onset HL. However, as research on OM in later childhood and beyond is lacking, the findings from this work help to address gaps in knowledge.

Although mild to moderate CHL in childhood is most commonly due to OM, we cannot be certain that every case is OM related. As no other measure of OM was analysed, the estimate of OM related HL may be an overestimate. In addition, there is the limitation of ALSPAC now being an older cohort when considering childhood HL and its implications at the present time. While treatment and management of OM has not changed much since the 1990s and early 2000s, there have been changes to the measures of academic achievement as well as an increase in mental health issues experienced by children and adolescents, particularly for emotional disorders including depression and anxiety (NHS Digital, 2018). While standardised tests of academic achievement and IQ have been revised over the years, these are standardised and are scored based on the overall performance of the sample being tested (the sample selected when revising IQ tests). Therefore, although performance may vary within samples from different time periods, the standardisation allows the identification of discrepancies in scores for children relative to their peers within that time period. The findings from ALSPAC in relation to mental health thereby may not be representative of the current generation. Nevertheless, no other studies have examined longitudinal data in order to study long-term OM related HL and its impact on a range of developmental outcomes in a sample as large as ALSPAC and utilising robust measures. Specific strengths and limitations for each piece of work in this thesis are detailed in each designated chapter presenting each piece.

9.3 Implications of the findings and suggestions for future research

HL prevalence findings presented in this thesis suggest that 1 in 50 children experience a long-term CHL between the ages of 7-15 years. This is much greater than the reported prevalence of

permanent HL in 1.33 per 1000 children aged 5 years and above and 1.65 per 1000 children aged 9 years and above (Fortnum et al.; Fortnum et al., 2001). Although this 2.69% HL is not permanent, by analysing the presence of HL at 2 or more time points, the finding represents the proportion of children who experience persistent or recurrent HL over 2 or more years. This figure presents with implications for public health and clinical practice. The importance of providing appropriate intervention and support for these children is reflected in the on-going nature of HL over a number of years stemming from a commonly known temporary childhood condition. This is further highlighted by the associations between this long-term OM related CHL and IQ at age 15 as this HL is shown to impact cognitive ability.

In clinical practice and as research has shown, OM related HL is thought to be more prevalent in the earlier years of childhood and resolve as time progresses. However, by studying the HL patterns in this ALSPAC sample, it has been shown that the timing of CHL is not predictable, with children experiencing HL on and off through the time period studied and some acquiring late onset HL around the ages of 11 to 15 years. The need to identify these later cases of acquired HL if they have not already been identified earlier on in order to provide support and to work to prevent any negative effects of the HL is highlighted. Where hearing data was missing in ALSPAC or at ages where data was not collected, we do not know if the child had HL. Yet, there were a number of children who presented with normal hearing at two or more time points, indicating the fluctuating nature of the HL. In practice, these children when presenting with normal hearing would be discharged from ENT and audiology services and their on-going hearing status would not be monitored. As the ALSPAC data show, the HL may return years later for some children which may be unexpected given the information provided about OME being a temporary condition.

Regarding information provided for children who present with OME in clinical practice, particularly for those whose OME and HL does not resolve upon the first set of treatment, it needs to be clear that there is the potential for HL to be on-going. This may require parents to continue to be vigilant

about their child's hearing in order for their hearing levels to be monitored. Furthermore, there is the need to inform parents of potential HL implications, which as presented in this thesis include the impact on cognitive ability. It should be highlighted that efforts should be made at home to optimise the home cognitive learning environment as well as with informing schools to optimise the child's learning experience as children require support to prevent the implications to their cognitive abilities.

While the findings provide evidence for considering the role of this HL and putting in place measures to detect this HL e.g. school hearing screening, so that children who develop HL later in life are not missed, the cost-effectiveness debate exists. Furthermore, the ALSPAC findings present acquiring CHL at ages as late as 11 and 15 years, so these children would be missed by hearing screening at school entry at 4/5 years, therefore, a number of screening programmes may be needed. What may be more feasible is educating clinicians, teachers and the general public on the nature of this long-term OM related HL and its impact, such that when a child develops OM, it is not overlooked as a temporary condition but a cause of potential long-term HL, with precautions being taken and support provided rather than solely waiting for the OM to resolve. As indicated in this thesis, resolution of OM related HL is not always the case.

The ALSPAC sample in which the prevalence of long-term OM related HL was studied, as mentioned was a socially advantaged sample, thus the figure of 2.69% may be an underestimate of the prevalence in the general population as the risk of OM is higher in children who come from low socioeconomic backgrounds (Schilder et al., 2016). Furthermore, as this estimate is of long-term OM related HL in children from around 20 years ago, we cannot be certain that this estimate is representative of the proportion of children with long-term OM related HL in more recent years and relevant for current health policies. While the management of OME has not changed much overtime, studies have reported a decline in cases of OM since the 1990s which is particularly due to clinical guidance recommendation of the use of antibiotics to treat AOM (from which OME can develop) and

the introduction of the pneumococcal conjugate vaccine (Schilder et al., 2016). This infers that at present, the prevalence of long-term OM related HL may possibly be lower. However, despite this uncertainty, OM remains a common childhood condition and the work in this thesis has revealed that some children experience an on-going or fluctuating OM related HL over the space of 2-9 years beyond the age of 7 which influences cognitive ability.

More recent qualitative studies of the impact of OME related HL have demonstrated effects on psychosocial aspects of children's development and their educational experiences, indicating that during more recent years, long-term OME related HL is impacting children in these domains. This indicates that more up to date research is needed to study the impact of long-term OME related HL. Future studies should seek to study outcomes which measure the quality of achievement grades rather than the quantity, to study whether children with long-term OM related HL are reaching their potential, ideally with a diverse sample. In this thesis it was not seen whether children had more difficulty in literacy-based subjects to reflect the poorer verbal IQ, thus outcomes measuring academic skills should be selected.

In addition, the psychosocial outcomes selected in this thesis reflected the development of mental health issues. Future studies should adopt measures of psychosocial functioning pertaining to self-esteem and social behaviour at school as these may be mediating factors which put children at greater risk of developing mental health issues (Mann et al., 2004; Thoits, 1999; Juth et al., 2008). Qualitative methods should also be utilised to obtain a greater understanding of how long-term OME related HL impacts the lives of children, for which ethically approved suggestions have been provided in the previous chapter. The research should ensure to engage those that have been affected by long-term OME related HL as well as key individuals who are involved their lives. Furthermore, a life course approach should be taken to study prevalence and impact of long-term OM related HL as analyses revealed OM related HL being prevalent at all four time points studied.

This research will aid in identifying the appropriate information required by children who initially present with OM as well as the support required by children with long-term OM related HL.

The information presented in this thesis provides needed data on long-term OM related HL. This HL as a long-term condition cannot be cured and its on-going or fluctuating nature suggests that it cannot be sufficiently controlled. In terms of suggestions for intervention for children with long-term OM related HL, research into other forms of treatment for OME should continue as children are seen to experience on-going HL after failed treatment with ventilation tubes. This thesis presents evidence of long-term OME related HL occurring into adolescence, which provides the basis for further exploration.

9.4 Conclusion

This thesis adds to existing epidemiological knowledge on childhood HL, identifying that over 2% of children experience on-going CHL associated with OM beyond the age of 7. While this HL was not found to impact mental health, there is evidence of its impact on cognitive ability in adolescence, but not to the extent of influencing the standard targeted academic achievement for students at the end of their secondary education. Future work should investigate further to compare effects across the life span and identify the support needs of these children to provide timely intervention.

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Appendices

Appendix A. Data abstraction form for Systematic Review

Paper	**Otitis media in childhood in relation to preschool language and school readiness skills among black children.**	**Otitis media in early childhood in relation to children's school-age language and academic skills**	**Otitis media and academic achievements**	**Behaviour and developmental effects of otitis media and developmental effects into the teens**	**Glue ear, hearing loss and IQ: An association moderated by the child's home environment**	**Silent reading and secretory otitis media**
Author(s)	Roberts JE, Burchinal MR, Jackson SC, Hooper SR, Roush J, Mundy M, Neebe EC, Zeisel SA.	Roberts JE, Burchinal MR, Zeisel SA	Augustsson I & Engstand I	Bennett KE, Haggard MP, Silva PA, Stewart IA.	Hall AJ, Maw R, Midgley E, Golding J, Steer C.	Lous, J
Year	2000	2002	2001	2001	2014	1993
Country	USA	USA	Sweden	New Zealand	UK	Denmark
Purpose/objective	To examine whether otitis media with effusion (OME) and associated hearing loss during the first 5 years of life were related to children's language skills during the preschool years and to school readiness skills at	To examine whether otitis media with effusion (OME) and associated hearing loss during the first 4 years of life are related to the language development and academic achievement of children between 4 years of age and second grade.	To study whether there are any long-term differences in academic achievements between children with and without observed or treated middle ear disease in a population with a	To examine whether behavioural or cognitive sequelae of otitis media with effusion (OME) continue into late childhood and the early teens (11-18 years).	To examine the association between a score comprising the number of times a child had OME and HL (OME/HL score) in the first four/five years of life and IQ at age 4 and 8. To examine whether any association between OME/HL and IQ is moderated by	To look for an association between otitis media and reading disability, and to compare the power of any such association with other risk factors for reading skill deficits.

	entry to kindergarten.		stable long-standing treatment policy		socioeconomic, child or family factors.	
Design	Prospective cohort study	Prospective cohort study	Prospective birth cohort study	Longitudinal birth cohort study	Longitudinal birth cohort study	Prospective cohort study
Population	African American infants primarily from low-income families who attended group child-care centers	African American children primarily from low income families recruited from 9 country based childcare programmes	Swedish children from Örebro, born in 1980 and have been living in the area between 1984 and 1995.	Dunedin Cohort Births between 1 April 1972 and 31 March 1973 in Dunedin City, New Zealand	10% random sample of children from ALSPAC, a longitudinal birth study on children born in Avon in Bristol, UK between 1 April 1991 and 31 December 1992	Children from two Danish municipalities in their first year of school. Attended one of 13 schools across these two areas
No. of participants	85	83	2095	1037	1155	366
Age of participants at start of study	6 months	6 months	4 years	Recruited at birth (OME history from age 5)	Recruited at birth (testing from 8 months)	7 years
Measure of OME/hearing	Pneumatic otoscopy and tympanometry weekly for first 15 months then biweekly between study entry and 5 years and then monthly in the last year. Hearing tested routinely on entry to study and every 3 months, during weeks 1, 4, 7 and 13 after OME diagnosis and after a change in ear status. VRA for 6	Pneumatic otoscopy and tympanometry weekly for first 15 months then biweekly between study entry and 5 years and then monthly in the last year. Hearing tested routinely on entry to study and every 3 months, during weeks 1, 4, 7 and 13 after OME diagnosis and after a change in ear status. VRA for 6 months - 2.5-year olds. Play audiometry between 2.5 and 4 years.	Oto-microscopy, audiometry and tympanometry from medical and ENT records. Three groups: Treated SOM, Mild SOM and Healthy	Tympanometry and otomicroscopy to determine ear status. Audiometry to assess hearing levels	Tympanometry to detect OME. McCormick Toy Test to test hearing acuity	Pneumatic otoscopy. Pure tone screening was done at 15 dB at the first test and at 10 dB at the later 4 tests, with 8 frequencies. Impedance audiometry was performed ten times during the year

	months - 2.5 year olds. Play audiometry between 2.5 and 4 years.					
Age OME/hearing measured	OME from 6 months to 5 years. Hearing from 6 months to 4 years	OME from 6 months to 5 years. Hearing from 6 months to 4 years	4, 7, 11 & 14 years (ENT history from birth)	Between 5 and 9 years	Up to 5 years	7-8 years (over the course of the year)
Outcome measure	2 subtests from the Woodcock-Johnson Psychoeducational Battery (WJPB): Letter word identification & Applied problems	2 subtests from the Woodcock-Johnson Psychoeducational Battery (WJPB): Letter word identification & Applied problems	Grade achieved at end of 9th grade and chosen high school program - theoretical/vocational from Government Statistical Office	Verbal and non-verbal intelligence quotient (IQ) WISC scales at 11- and 13-years Dunedin spelling tests at 11 and 13 years, Burt reading test at 11, 13, 15, and 18 years	WISC scales to test IQ – Wechsler Pre-school and Primary Scale of Intelligence at age 4 and Wechsler Intelligence Scale for Children, WISC-III at age 8	Silent Reading Word Test (OS-400)
Age outcome measured	Entry into kindergarten - 5 years	Once a year between 4 years and second grade (8 years)	9th grade - 15/16 years	11-18 years	4 years and 8 years	8 years
Confounders	Gender, poverty, maternal education, average HOME total score (home environment) and average ITERS/ECERS scores (childcare classroom environment)	Gender, maternal education, average HOME total score (home environment)	Sex and other diseases (total days spent in hospital care)	Sex, socioeconomic status	Sex, birthweight, gestational age, SES, maternal age, parity and smoking in pregnancy, cognitive environment at home, parenting style	N/A
Statistical analysis	Linear Regression	Pearson correlations, General linear mixed models	Linear and Logistic Regression	Linear Regression	Linear Regression	Linear regression

Key result	OME and HL moderately correlated with school readiness skills - children with more OME scoring lower in verbal math problems ($p<0.01$) and children with more HL scoring lower in math ($p<0.01$). Remained significant after adjustment for gender, SES, maternal education and home and childcare factors. Home environment more strongly related to academic outcomes. HOME and childcare environment did not mediate associations.	No significant relationship between OME and hearing loss and early reading and recognition of words heard in first 4 years of life. But children with greater incidence of OME ($p<0.01$) and hearing loss ($p<0.001$) during first 4 years of life scored lower in verbal math problems between kindergarten and second grade and children with OME tended to score lower (non-significantly) in math problems but caught up once they started school. Children with more OME during first 2 years of life scored significantly lower in math (OME $p<0.03$) (HL $p<0.049$). When adjusted for confounders, children from homes rated as more stimulating and responsive scored higher on every measure of language and academic skills than those from lower responsive homes ($p<0.01$).	Children with OME had lower grades than healthy children however, this was not significant. No difference in choice of course.	Associations with OME history up to age 9 were with found to be strongest with verbal IQ at 11 ($p <.01$) and 13 years ($p <.001$), non-verbal ($p<.01$) and full IQ ($p<.001$) at 13 years, reading deficits at 11, 13, 15, and 18 years ($p<.01$), and spelling at 13 years ($p<.01$). After adjusting for sex and SES, in repeated measures analysis, children's ear condition by age 9 had little effect on mean reading score.	At age 4 there was evidence of a strong association between OME/HL group and both verbal and performance IQ $p\leq.001$. At age 8 relationships were weak or had no statistical significance. HOME scores at age 6, 18 and 42 months were significant moderators of the effect of OME/HL score on verbal IQ at age 4 $p <.01$. HOME scores at 6, 18, 30 and 42 months were significant moderators on performance IQ at age 4 $p <.01$. HOME scores at 18- and 30-months $p<.01$ and parenting score at 38 months were significant moderators of the effect of OME/HL score on verbal IQ at age 8 $p<.05$. HOME scores at 18- and 30-months $p\leq.01$ and parenting at 6 months were significant moderators on performance IQ $p<.05$ at age 8.	No significant relation between the silent reading score and mean hearing level however, a small but significant relation between reading score and type B in the boys ($P = 0.04$), but not in the girls

Appendix B. Risk of bias tables for the studies selected for systematic review

Augustsson & Engstand (2001) – Otitis media and academic achievements

	Definitely yes (low risk of bias)	Probably yes	Probably no	Definitely no (high risk of bias)	Justification
1. Was selection of exposed and non-exposed cohorts drawn from the same population?	X				Exposed and non-exposed participants were from the same cohort of Swedish children (from same area) who had audiometric screening carried out at ages 4, 7, 11 & 14 years. All children were born in 1980 and had been living in the area (Orebro) between 1984 and 1995.
2. Can we be confident in the assessment of exposure?	X				Children who had impaired hearing at the screenings were referred to ENT clinics after 6-8 weeks and if not already being seen by ENT for SOM were seen by ENT again 12-14 weeks after the screening. If SOM was still present, they were followed and treated. Policy is to refer to ENT if SOM has not resolved after 3 months. Hence, these children meet the criteria of experiencing long-term OM & HL. Assessment of exposure obtained from ENT medical records. *"We registered contact for ear disease and treatment with ventilation tubes in the right and the left ear in each 2-year period up to the age of 14 years. Thus, there are medical records for children who have had impaired hearing due to SOM at one or more of four screening occasions and for children who*

					have consulted a doctor because of symptoms, and whose SOM has not resolved in 3 months."
3. Can we be confident that the outcome of interest was not present at start of study?	X				The outcome was grades obtained at the end of the ninth grade (15/16 years). The study (measure of exposure) started when children were 0-4 years old.
4. Did the study match exposed and unexposed for all variables that are associated with the outcome of interest or did the statistical analysis adjust for these prognostic variables?				X	While the study adjusted for sex (and days spent in hospital), it did not adjust for other relevant confounders e.g. maternal education/SES, ethnicity
5. Can we be confident in the assessment of the presence or absence of prognostic factors?	X				The information was taken from another file on child's health information
6. Can we be confident in the assessment of outcome?		X			Grades based on national standardizing exams and performance markings on schoolwork. However, to some extent on the teachers rating of the student's classroom behaviour and attitude – grades thus may be biased if teacher rates child based on poor behaviour, nonetheless OM related HL may have influenced behaviour and hence grades obtained.

7. Was the follow up of cohorts adequate?		X			2127 children with ENT files up to 14 years. 2095 of these children had outcomes data: *"Of the 2127 children, 2095 who, as far as we know, have attended the compulsory nursery and middle school could be retrieved in this file."* Missing data unrelated to exposure. No other details on missing data given, however when totalling the number of children in each exposure group – gives a number of 2,048 (3.71% missing data) – no details on missing data given here.
8. Were co-interventions similar between groups?					N/A

Bennett et al. (2002) - Behaviour and developmental effects of otitis media with effusion into the teens

	Definitely yes (low risk of bias)	Probably yes	Probably no	Definitely no (high risk of bias)	Justification
1. Was selection of exposed and non-exposed cohorts drawn from the same population?	X				Longitudinal cohort study - children born in Dunedin, New Zealand, between 1 April 1972 and 31 March 1973.
2. Can we be confident in the assessment of exposure?	X				*"The otological status of the child, defined from age 5 to 9 years in the Dunedin study, provides an objective measurement of the cumulative history of OME, thus enabling us to exclude those with earlier but shorter term histories."* Otological status defined through otomicroscopy, impedance audiometry, and pure tone audiometry carried out at 5, 7, 9, 11, 13, and 15 years
3. Can we be confident that the outcome of interest was not present at start of study?	X				Outcomes were age specific: verbal and non-verbal intelligence quotient (IQ) at 11- and 13-years spelling ability at 11 and 13 years and reading ability at 11, 13, 15, and 18 years.
4. Did the study match exposed and unexposed for all variables that are associated with the outcome of interest or did the statistical analysis adjust for				X	While the study adjusted for sex and socioeconomic group, potential confounding specific to maternal education level for example was not accounted for.

these prognostic variables?					
5. Can we be confident in the assessment of the presence or absence of prognostic factors?		X			The paper does not describe how information regarding these factors were obtained, however, other studies on the Dunedin cohort have described that socioeconomic information was obtained through parental report at ages 3, 5, 7, 9, 11, 13, and 15 years.
6. Can we be confident in the assessment of outcome?	X				Standardised measures used to obtain IQ and reading ability. Dunedin spelling test not standardised.
7. Was the follow up of cohorts adequate?				X	Did not describe attrition rates. Attrition is expected with a longitudinal study.
8. Were co-interventions similar between groups?					N/A

Hall et al. (2014) - Glue Ear, Hearing Loss and IQ: An Association Moderated by the Child's Home Environment

	Definitely yes (low risk of bias)	Probably yes	Probably no	Definitely no (high risk of bias)	Justification
1. Was selection of exposed and non-exposed cohorts drawn from the same population?	X				All children part of ALSPAC – born in Avon, UK between 1st April 1991 and the 31st December 1992. *"This study comprised the Children in Focus (CiF) group, a 10% sample of the ALSPAC cohort who attended clinics at the University of Bristol at various time intervals between 4 to 61 months of age. The CiF group were chosen at random from the last 6 months of ALSPAC births (1432 families attended at least one clinic)."*
2. Can we be confident in the assessment of exposure?		X			Tympanometry to test middle ear function up to age 5 (at 8, 12, 18, 25, 31, 37, 43, 49 and 61 months) and measures of word recognition threshold using a test of the binaural ability to hear speech, the Automated McCormick Toy Test at 2.5, 3 .5 and 5 years. Not a direct measure of hearing ability but strongly related to hearing ability and used to detect hearing loss in young children. But hearing not assessed at all time points that middle ear function was tested – but as focusing on hearing loss, focus is on ages where hearing was assessed.
3. Can we be confident that the outcome of interest was not	X				Outcomes were age specific: Verbal and performance IQ measured at 4 years and 8 years.

present at start of study?					
4. Did the study match exposed and unexposed for all variables that are associated with the outcome of interest or did the statistical analysis adjust for these prognostic variables?		X			Socioeconomic factors: highest maternal education level achieved; housing tenure and parental social class Maternal and child factors: maternal age; parity; smoking in 1st three months of pregnancy; smoking in last two weeks of pregnancy; birthweight; gestational age and sex of child. Cognitive home environment and parenting style Did not consider ethnicity, although sample was predominantly White.
5. Can we be confident in the assessment of the presence or absence of prognostic factors?	X				Information on a range of factors were collected from mother's in ALSPAC, either via questionnaire or in clinic.
6. Can we be confident in the assessment of outcome?	X				Standardised measures used to obtain IQ
7. Was the follow up of cohorts adequate?				X	Attrition rates for outcomes: 4.5 years – 24.7% 8 years – 36.6% Attrition for exposure was 19.57%, 13.77% & 19.91% at 2.5 years, 3.5 years and 5 years, respectively.
8. Were co-interventions similar between groups?					NA

Lous (1993)

Silent reading and secretory otitis media

	Definitely yes (low risk of bias)	Probably yes	Probably no	Definitely no (high risk of bias)	Justification
1. Was selection of exposed and non-exposed cohorts drawn from the same population?	X				All children recruited from two areas of Denmark. All were children attending school in the first grade. Children attending 13 schools across the two areas of Denmark
2. Can we be confident in the assessment of exposure?			X		Hearing only screened on half of the number of occasions that tympanometry was carried out. Furthermore, the author reported that only 8% of children experienced OM for 3 months or longer with only few children having longstanding hearing loss. Therefore, study may not be representative of children with long-term OME related HL

3. Can we be confident that the outcome of interest was not present at start of study?			X		Outcome measure is not age specific like measures developed to test abilities at specific ages.
4. Did the study match exposed and unexposed for all variables that are associated with the outcome of interest or did the statistical analysis adjust for these prognostic variables?				X	Did not adjust for confounders in analysis of hearing level but did with tympanograms. However, we are interested in hearing level analysis.
5. Can we be confident in the assessment of the presence or absence of prognostic factors?				X	Factors not considered in hearing loss analysis.
6. Can we be confident in the assessment of outcome?		X			High test-retest reliability and strong correlation with teachers' opinion on the student's abilities to understand a written text. No details given about scoring of outcome and whether age-specific.
7. Was the follow up of cohorts adequate?		X			Only 5% attrition due to children moving out of area or moving

					grades or being absent from school on day of reading assessment. School absence may be associated with outcome, however.
8. Were co-interventions similar between groups?					NA

Roberts et al (2000, 2002)

Otitis Media in Early Childhood in Relation to Preschool Language and School Readiness Skills Among Black Children

Otitis Media in Early Childhood in Relation to children's school-age language and academic skills

	Definitely yes (low risk of bias)	Probably yes	Probably no	Definitely no (high risk of bias)	Justification
1. Was selection of exposed and non-exposed cohorts drawn from the same population?	X				All children were African American children recruited from 9 centre-based childcare programs between 6 and 12 months of age over a 20-month period.
2. Can we be confident in the assessment of exposure?	X				Pneumatic otoscopy and tympanometry weekly for first 15 months then biweekly between study entry and 5 years and then monthly in the last year. Hearing tested routinely on entry to study and every 3 months, during weeks 1, 4, 7 and 13 after OME diagnosis and after a change in ear status
3. Can we be confident that the outcome of interest was not present at start of study?	X				Outcomes were age specific, measured prospectively between 4 and 8 years of age. Tests of academic skills which cannot be tested at start of study when children were between 6 and 12 months of age.
4. Did the study match exposed and unexposed for all variables that are associated with the outcome of interest or		X			The analyses in this study adjusted for gender, whether the family lived in poverty, highest grade of school mother completed, and the responsiveness and support of the home and childcare environments. The majority of the sample were from low

did the statistical analysis adjust for these prognostic variables?					economic backgrounds and were African American (one was Native American). "*All children had no known medical or genetic abnormalities when entering the study. Sixty-seven children were born at full gestational age (>37 weeks); 11 were born at 37 weeks and 1 at 30 weeks of gestational age."* Noted family income, mother's age, who child lived with, highest level of education obtained by the caregivers and mean IQ of primary guardian.
5. Can we be confident in the assessment of the presence or absence of prognostic factors?	X				*"At entry into the study, 72.9% of the families were classified as low-income based on whether family income was <185% of the federal poverty threshold income."* No specific detail on the measure used to obtain maternal education information but maternal education at group level reported. Quality and responsiveness of home environment measured using HOME Inventory – has high levels of validity and reliability. *Over the 5-year period, home visits were conducted by 2 trained nurse practitioners and 2 speech-language pathologists who had achieved interrater agreement of at least 95% before collecting the data.* Quality of the caregiver and of the physical environment in each child's classroom in childcare assessed using ITERS and ECERS – high levels of validity and reliability. Examiner was blind to child's OME and hearing status. "*1 of 5 trained observers who had achieved*

					good interrater reliability with the test developers and trained ITERs observers did the observations. “
6. Can we be confident in the assessment of outcome?	X				Standardised measures used to assess cognitive ability and academic skills. Assessors were blind to OME and hearing status.
7. Was the follow up of cohorts adequate?		X			Did not describe attrition rates. But in later study, sample decreased by 2 (after 5 years).
8. Were co-interventions similar between groups?					NA

Appendix C. DAWBA questions for mental health measures (anxiety at 10 and 15 years, depression at 15 years)

Parental questionnaire at 10 years:

SECTION F: SOCIAL FEARS

F1. Overall does your study child particularly fear or avoid situations that involve a lot of people or meeting new people or doing things in front of people? **Do not count the occasional "off day" or ordinary shyness.**

Yes [1] No [2]

F2. Has he been particularly afraid of any of the following situations over the last month?

	Afraid of:	No	A little	A lot	Hasn't done this in last month
a)	Meeting new people	1	2	3	4
b)	Meeting a lot of people such as at a party	1	2	3	4
c)	Speaking in class	1	2	3	4
d)	Reading out loud in front of others	1	2	3	4
e)	Writing in front of others	1	2	3	4
f)	Eating in front of others	1	2	3	4

* **If you have ticked 'a lot' to ANY of the answers in F2 above, continue below. If not, go to G1 on page 26**

F3. Are his fears of being with a lot of people mainly related to his fear of being separated from someone he is attached to, or are the fears still there even when he is with such a person?

mainly afraid only when separated from his special people [1] afraid even when with one of his special people [2]

F4. Is your study child just afraid in these situations with adults, or is he also afraid in situations that involve lots of children, or meeting new children?

only with adults [1] with both adults and children [2] only with children [3]

F5. Outside of these situations is your study child able to get on well enough with the adults and children he knows best?

Yes [1] No [2]

F6. a) Do you think his dislike of these situations is because he is afraid he will act in a way that will be embarrassing or show him up?

Yes, definitely [1] Not sure [2] No [3]

b) Is it related to speech, reading or writing problems?

Yes [1] Not sure [2] No [3]

c) Why else do you think he dislikes such situations? .....

.....

F7. a) How long has he had this fear of being with lots of people, or doing things in front of lots of people, or meeting new people?

less than one month [1] 1-5 months [2] 6 months or more [3]

b) What age did it begin?

under 6 years [1] 6 years or older [2]

F8. When your study child is in one of these situations he fears, or when he thinks he is about to be in one, how anxious or upset does he usually become?

very anxious or upset [1] just a bit [2] not at all [3] → **If '<u>not at all</u>' go to F10 on on page 25**

F9. How often do these fears result in his becoming upset like this?

Many times a day [1] Most days [2] Most weeks [3] Every now and then [4]

F10. a) Does his fear lead to avoiding these situations?

yes, a lot [1] a little [2] no [3]

If '<u>a little</u>' or '<u>no</u>' go to F10c below

b) Does this avoidance interfere with his everydaylife?

no [1] a little [2] yes, a lot [3]

c) Does he recognise that this fear is excessive or unreasonable?

no [1] perhaps [2] definitely [3]

d) Is he upset about having this fear?

no [1] perhaps [2] definitely [3]

F11. Has your study child's fear of these situations put a burden on you or the family as a whole?

not at all [1] a little [2] quite a lot [3] a great deal [4]

a) Space for comments

.....

.....

.....

SECTION J: ANXIETY IN GENERAL

Nearly all children have some worries, and these are naturally worse on some days than others, but some children have so many worries for so much of the time that it makes them really upset or interferes with their lives.

J1. Does your study child ever worry?

Yes [1] No [2] → **If no, go to K1 on page 35**

J2. Apart from any of the specific anxieties already mentioned on previous pages, has he worried so much over the last six months about so many things that it has really upset him or interfered with his life?

Definitely [1] Perhaps [2] No [3]

J3. Does he worry a lot about:

	No, not at all	Sometimes	Often
a) Past behaviour (e.g. Did I do that wrong? Have I upset someone? Have they forgiven me?)	1	2	3
b) School work, homework or tests/ examinations	1	2	3
c) Disasters (e.g. burglaries, muggings, fires, bombs)	1	2	3
d) His own health	1	2	3
e) Bad things happening to others (e.g. family, friends, pets, the world)	1	2	3
f) The future (e.g. changing school, growing up, getting a job)	1	2	3
g) Any other worries? (please tick and describe)	1	2	3

.....

J4. In the past 6 months has he worried excessively on more days than not?

Yes [1] No [2]

J5. Does he find it difficult to control the worry?

Yes [1] No [2]

J6. a) Does worrying lead to his being restless, feeling keyed up, tense or on edge, or being unable to relax?

No not at all [1] Yes, but not on most days [2] Yes happens more days than not [3]

b) Does worrying lead to his feeling tired or "worn out" more easily?

No not at all [1] Yes, but not on most days [2] Yes happens more days than not [3]

c) Does worrying lead to difficulties in concentrating or his mind goingblank?

No not at all [1] Yes, but not on most days [2] Yes happens more days than not [3]

d) Does worrying lead to irritability?

No not at all [1] Yes, but not on most days [2] Yes happens more days than not [3]

e) Does worrying lead to his looking physically tense (tense muscles)?

No not at all [1] Yes, but not on most days [2] Yes happens more days than not [3]

f) Does worrying interfere with his sleep (e.g. difficulty in falling or staying asleep, or restless sleep, or doesn't have a good night's sleep)?

No not at all [1] Yes, but not on most days [2] Yes happens more days than not [3]

Not at all [1] A little [2] Quite a lot [3] A great deal [4]

J8. Have these worries interfered with his day-to-daylife?

Have they interfered with:	**No, not at all**	**Only a little**	**Quite a lot**	**A great deal**
a) how well he gets on with you and the rest of the family	[1]	[2]	[3]	[4]
b) making and keeping friends	[1]	[2]	3	[4]
c) learning or school work	[1]	[2]	3	[4]
d) playing, hobbies, sports or other leisure activities	[1]	[2]	[3]	[4]

J9. Have these worries put a burden on you or the family as a whole?

Not at all [1] A little [2] Quite a lot [3] A great deal [4]

a) Space for comments

.....

.....

.....

Clinic interview questions at 15 years:

TF3 File – Interview Session

Teen Focus 3 **DAWBA Interview** **FORM DITF3** **Version 1** **10.10.06**

Visit Number

DI1 Session Start Time ☐☐ : ☐☐

DI2 Visit Date ☐☐ / ☐☐ / 2 0 0 ☐

DI3 Staff ☐☐☐ DI4 Room 1☐ 2☐ 3☐ 4☐

DI5 Interview Started? Y☐ N☐

"I'm going to ask you some questions about your moods and feelings especially regarding times when you were particularly upset or anxious. There are no right or wrong answers and your name is not on this piece of paper, so no one else will even know that these answers are yours, OK? It's also important for you to remember that we won't tell anyone what you tell me, unless you tell us about you or someone else who may be in danger and then we may have to tell someone who can try and help, OK?"

SECTION A: Fear of social situations

"I am interested in whether you are particularly afraid of social situations. This is as compared with other teenagers of your own age, and is not counting the occasional 'off day' or ordinary shyness"

DIA1 **Overall, do you particularly fear or avoid social situations that involve a lot of people, meeting new people, or doing things in front of other people?** No☐ Yes☐

If DIA1 = 'yes', then continue. If DIA1 = 'no', then skip to section B

DIA2 **Have you been particularly afraid of any of the following social situations over the last 4 weeks?**

		No	A little	A Lot
DIA2a	**Meeting new people?**	1☐	2☐	3☐
DIA2b	**Meeting a lot of people, such as at a party?**	1☐	2☐	3☐
DIA2c	**Eating in front of others?**	1☐	2☐	3☐
DIA2d	**Speaking in class?**	1☐	2☐	3☐
DIA2e	**Reading out loud in front of others?**	1☐	2☐	3☐
DIA2f	**Writing in front of others?**	1☐	2☐	3☐

DIA3 **Most young people are attached to a few key adults, feeling more secure when they are around. Some young people are only afraid of social situations if they don't have one of these key adults around. Other young people are afraid of social situations even when they are with one of these key adults. Which is true for you?**

Mostly fine in social situations as long as key adults are around 1☐

Social fears are marked even when key adults are around 2☐

DIA4 **Are you just afraid with adults or are you also afraid in situations that involve a lot of young people, or meeting new people of your own age?**

Just with adults 1☐ Just with young people 2☐ With both adults and young people 3☐

DIA5 **Outside of these social situations, are you able to get on well enough with the adults and young people you know best?** No☐ Yes☐

DIA6 **Is the main reason you dislike social situations because you are afraid you will act in a way that will be embarrassing or show you up?**

No 1☐ Perhaps 2☐ Definitely 3☐

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Teen Focus 3 **DAWBA Interview** **FORM DITF3** **Version 1** **10.10.06**

Only ask DIA7 if the answer to DIA2d or DIA2e or DIA2f = 'A lot'

DIA7 **Do you dislike social situations because of specific problems with speaking, reading or writing?** No 1☐ Perhaps 2☐ Definitely 3☐

DIA8 **How long has this fear of social situations been present?**

Less than 1 month 1☐ 1-5 months 2☐ 6+ months 3☐

DIA9 **How old were you when this fear of social situations began?** *(If since birth, enter 00)* ☐☐ Years old

DIA10 **When you are in one of the social situations you are afraid of, do you normally…**

DIA10a **Blush (go red) or shake (tremble)?** No☐ Yes☐

DIA10b **Feel afraid that you are going to be sick (throw up)?** No☐ Yes☐

DIA10c **Need to rush off to the toilet or worry that you might be caught short?** No☐ Yes☐

DIA11 **When you are in one of the social situations you are afraid of, or when you think you are about to come up against one of these situations, do you become anxious or upset?**

No 1☐ A little 2☐ A lot 3☐

If the answer to DIA11 is either 'no' or 'a little' go to question DIA13.
If the answer to DIA11 is 'A lot', go to question DIA12.

DIA12 **How often does your fear of social situations result in you becoming upset like this?**

Every now and then 1☐ Most weeks 2☐ Most days 3☐ Many times a day 4☐

DIA13 **Does your fear lead to you avoiding social situations?** No 1☐ A little 2☐ A lot 3☐

If the answer to DIA13 is 'No' or 'A little' go to question DIA15.
If the answer to DIA13 is 'A lot', go to question DIA14.

DIA14 **Does this avoidance interfere with daily life?** No 1☐ A little 2☐ A lot 3☐

DIA15 **Do you think your fear of social situations is over the top or unreasonable?**

No 1☐ Perhaps 2☐ Definitely 3☐

DIA16 **Are you upset about having this fear?** No 1☐ Perhaps 2☐ Definitely 3☐

DIA17 **Has your fear of social situations made it harder for those around you (family, friends, teachers etc.)?**

Not at all 1☐ A little 2☐ A medium amount 3☐ A great deal 4☐

SECTION B: Depression

"This section of the interview is about your mood."

DIB1 **In the last 4 weeks have there been times when you have been very sad, miserable, unhappy or tearful?** No☐ Yes☐

If the answer to DI B1 is 'no', then move to question DI B6. If the answer is yes, then continue.

DIB2 **Over the last 4 weeks has there been a period when you have been really miserable nearly every day?** No☐ Yes☐

DIB3 **During the time when you have been miserable, have you been miserable for most of the day?** No☐ Yes☐

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Teen Focus 3 DAWBA Interview FORM DITF3 Version 1 10.10.06

DIB4 **When you have been miserable, could you be cheered up?**

Easily 1 ☐ With difficulty/only briefly 2 ☐ Not at all 3 ☐

DIB5 **Over the last 4 weeks, the period of being really miserable has lasted:**

Less than 2 weeks 1 ☐ 2 weeks or more 2 ☐

If the answers to DIB1, B2 and B3 are all 'yes' then cross this box: **Box 1** 1 ☐

"I've asked you about your mood in the last month, now thinking about the last 7 days..."

DIB6 **In the past week have you had a spell of feeling sad, miserable or depressed?** No ☐ Yes ☐

If the answer to DIB6 is 'no', then move to question DIB11.
If the answer is yes, then continue.

DIB7 **In the past week have you been able to enjoy or take an interest in things as much as usual?** No ☐ Yes ☐

DIB8 **Since last (DAY OF WEEK) on how many days have you felt sad miserable or depressed?**

4 days or more 1 ☐ 2-3 days 2 ☐ 1 day 3 ☐

DIB9 **Have you felt sad, miserable or depressed for more than 3 hours in total (on any day in the past week)?** No ☐ Yes ☐

DIB10 **In the past week when you felt sad, miserable or depressed did you ever become happier when something nice happened or when you were in company?** No ☐ Yes ☐

Irritability

"Now we are back to last month...."

DIB11 **In the last 4 weeks, have there been times when you have been grumpy or irritable in a way that was out of character for you?** No ☐ Yes ☐

If the answer to DIB11 is No, then skip to question DIB16.
If the answer is yes then continue with next question.

DIB12 **Over the last 4 weeks, has there been a period when you have been really irritable nearly every day?** No ☐ Yes ☐

DIB13 **During the period when you have been grumpy or irritable, have you been like that for most of the day (i.e. more hours than not)** No ☐ Yes ☐

DIB14 **Has the irritability been improved by particular activties, by friends coming round or by anything else?**

Easily 1 ☐ With difficulty/only briefly 2 ☐ Not at all 3 ☐

DIB15 **Over the last 4 weeks, the period of being really irritable has lasted:**

Less than 2 weeks 1 ☐ 2 weeks or more 2 ☐

If the answers to DIB11, B12 and B13 are 'yes' then cross this box: **Box 2** 1 ☐

Loss of interest

DIB16 **In the last 4 weeks, have there been times when you have lost interest in everything, or nearly everything, that you normally enjoy doing?** No ☐ Yes ☐

If the answer to DIB16 is no, then skip questions DIB17-19.
If the answer is 'yes' then continue with the next question.

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Teen Focus 3 DAWBA Interview FORM DITF3 Version 1 10.10.06

DIB17	**Over the last 4 weeks, has there been a period when this lack of interest has been present nearly every day?**	No ☐	Yes ☐
DIB18	**During these days when you have lost interest in things, have you been like this for most of each day? (i.e. more hours than not)**	No ☐	Yes ☐
DIB19	**Over the last 4 weeks, this loss of interest has lasted:**		
	Less than 2 weeks 1 ☐ 2 weeks or more 2 ☐		
	If the answers to DIB16 and DIB17 are 'Yes' then cross this box: **Box 3** 1 ☐		
	If there are ticks in TICKBOX 1, 2, OR 3 then continue with the following questions. If NONE of these separate tick boxes have been ticked, then skip to DIB24.		
DIB20	**During the period when you were sad, irritable or lacking in interest...**		
DIB20a	**Did you lack energy and feel tired all the time?**	No ☐	Yes ☐
DIB20b	**Were you eating much less than normal?** *If the answer is Yes go to DIB20d, if 'No' carry on*	No ☐	Yes ☐
DIB20c	**Were you eating much more than normal?**	No ☐	Yes ☐
DIB20d	**Did you lose a lot of weight?** *If the answer is Yes go to DIB20f, if 'No' carry on*	No ☐	Yes ☐
DIB20e	**Did you gain a lot of weight?**	No ☐	Yes ☐
DIB20f	**Did you find it hard to get to sleep or to stay asleep?**	No ☐	Yes ☐
DIB20g	**Did you sleep too much?**	No ☐	Yes ☐
DIB20h	**Were you agitated or restless for much of the time?**	No ☐	Yes ☐
DIB20i	**Did you feel worthless or unnecessarily guilty for much of the time?**	No ☐	Yes ☐
DIB20j	**Did you find it unusually hard to concentrate or to think things out?**	No ☐	Yes ☐
DIB20k	**Did you think about death a lot?** *(Concept of death)*	No ☐	Yes ☐
DIB20l	**Did you think about harming or killing yourself?**	No ☐	Yes ☐
DIB20m	**Did you try to harm yourself on purpose?** *(Clarify that was not part of an accident or experimentation)*	No ☐	Yes ☐
DIB20n	*(If Yes)* **Did you tell an adult?** *(clarify responsible adult knows)*	No ☐	Yes ☐
DIB20o	**Did you try to kill yourself?**	No ☐	Yes ☐
DIB20p	*(If Yes)* **Did you tell an adult?** *(clarify responsible adult knows)*	No ☐	Yes ☐
DIB20q	**Over the whole of your lifetime, have you ever tried to harm yourself or kill yourself?**	No ☐	Yes ☐
DIB20r	*(If Yes)* **Did you tell an adult?** *(clarify responsible adult knows)*	No ☐	Yes ☐
DIB21	**How much has your sadness, irritability or loss of interest upset or distressed you?**		
	Not at all 1 ☐ A little 2 ☐ A medium amount 3 ☐ A great deal 4 ☐		

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Teen Focus 3 DAWBA Interview FORM DITF3 Version 1 10.10.06

		Not at all	A little	A medium amount	A great deal
DIB22	**Has your sadness, irritability or loss of interest interfered with....**				
DIB22a	**How well you get on with the rest of the family?**	1 ☐	2 ☐	3 ☐	4 ☐
DIB22b	**Making and keeping friends?**	1 ☐	2 ☐	3 ☐	4 ☐
DIB22c	**Learning or class work?**	1 ☐	2 ☐	3 ☐	4 ☐
DIB22d	**Playing, hobbies, sports or other leisure activities?**	1 ☐	2 ☐	3 ☐	4 ☐
DIB23	**Has your sadness, irritability or loss of interest made it harder for those around you (family, friends, teachers etc)?**	1 ☐	2 ☐	3 ☐	4 ☐

GO TO SECTION C if you have already asked DIB20a - DIB20q

Deliberate self harm

DIB24	**Over the last 4 weeks have you thought about deliberately harming or hurting yourself?** *(Clarify that was not part of an accident or experimentation)*	No ☐	Yes ☐
DIB25	**Over the last 4 weeks have you tried to harm or hurt yourself?**	No ☐	Yes ☐
DIB25a	*(If Yes)* **Did you tell an adult?** *(clarify responsible adult knows)*	No ☐	Yes ☐
DIB26	**Over the whole of your lifetime have you ever tried to harm or hurt yourself?**	No ☐	Yes ☐
DIB26a	*(If Yes)* **Did you tell an adult?** *(clarify responsible adult knows)*	No ☐	Yes ☐

SECTION C: Generalized Anxiety

"This section is about worrying"

DIC1	**Do you ever worry?**	No ☐	Yes ☐

"Some young people worry about just a few things other young people worry about many different aspects of their lives. They may have specific fears but they also have a wide range of worries about many things."

DIC2	**Are you worried in general?**	No ☐	Yes ☐

DIC3 **Over the last 6 months have you worried so much about so many things that it has really upset you or interfered with your life?**

No 1 ☐ Perhaps 2 ☐ Definitely 3 ☐

		No more than others	A little more than others	A lot more than others
DIC4	**Thinking about the last 6 months, and comparing yourself with other people of your age, have you worried about...**			
DIC4a	**Past behaviour: Did I do that wrong? Have I upset someone? Have they forgiven me?**	1 ☐	2 ☐	3 ☐
DIC4b	**School work, homework or examinations?**	1 ☐	2 ☐	3 ☐
DIC4c	**Disasters: Burglaries, muggings, fires, bombs etc**	1 ☐	2 ☐	3 ☐
DIC4d	**Your own health**	1 ☐	2 ☐	3 ☐
DIC4e	**Bad things happening to others: family, friends, pets, the world (e.g. wars)**	1 ☐	2 ☐	3 ☐

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Teen Focus 3 DAWBA Interview FORM DITF3 Version 1 10.10.06

		Not at all	A little	A medium amount	A great deal
DIB22	**Has your sadness, irritability or loss of interest interfered with....**				
DIB22a	**How well you get on with the rest of the family?**	1 ☐	2 ☐	3 ☐	4 ☐
DIB22b	**Making and keeping friends?**	1 ☐	2 ☐	3 ☐	4 ☐
DIB22c	**Learning or class work?**	1 ☐	2 ☐	3 ☐	4 ☐
DIB22d	**Playing, hobbies, sports or other leisure activities?**	1 ☐	2 ☐	3 ☐	4 ☐
DIB23	**Has your sadness, irritability or loss of interest made it harder for those around you (family, friends, teachers etc)?**	1 ☐	2 ☐	3 ☐	4 ☐

GO TO SECTION C if you have already asked DIB20a - DIB20q

Deliberate self harm

DIB24	**Over the last 4 weeks have you thought about deliberately harming or hurting yourself?** *(Clarify that was not part of an accident or experimentation)*	No ☐	Yes ☐
DIB25	**Over the last 4 weeks have you tried to harm or hurt yourself?**	No ☐	Yes ☐
DIB25a	*(If Yes)* **Did you tell an adult?** *(clarify responsible adult knows)*	No ☐	Yes ☐
DIB26	**Over the whole of your lifetime have you ever tried to harm or hurt yourself?**	No ☐	Yes ☐
DIB26a	*(If Yes)* **Did you tell an adult?** *(clarify responsible adult knows)*	No ☐	Yes ☐

SECTION C: Generalized Anxiety

"This section is about worrying"

DIC1	**Do you ever worry?**	No ☐	Yes ☐

"Some young people worry about just a few things other young people worry about many different aspects of their lives. They may have specific fears but they also have a wide range of worries about many things."

DIC2	**Are you worried in general?**	No ☐	Yes ☐

DIC3 **Over the last 6 months have you worried so much about so many things that it has really upset you or interfered with your life?**

No 1 ☐ Perhaps 2 ☐ Definitely 3 ☐

		No more than others	A little more than others	A lot more than others
DIC4	**Thinking about the last 6 months, and comparing yourself with other people of your age, have you worried about...**			
DIC4a	**Past behaviour: Did I do that wrong? Have I upset someone? Have they forgiven me?**	1 ☐	2 ☐	3 ☐
DIC4b	**School work, homework or examinations?**	1 ☐	2 ☐	3 ☐
DIC4c	**Disasters: Burglaries, muggings, fires, bombs etc**	1 ☐	2 ☐	3 ☐
DIC4d	**Your own health**	1 ☐	2 ☐	3 ☐
DIC4e	**Bad things happening to others: family, friends, pets, the world (e.g. wars)**	1 ☐	2 ☐	3 ☐

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Aston University

A qualitative exploration of the impact of long-term otitis media with effusion and related hearing loss on children and adolescents and their information and support needs

Protocol Number: 263417

Version: 2.0

[January 2020]

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

Chief Investigator*:*	Dr. Amanda Hall
Co-investigators:	Aleema Rahman Dr. Helen Pryce Dr. Rachel Shaw
Sponsor:	Aston University

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14. Signatures

1. Background and rationale

Otitis media with effusion (OME – also known as glue ear) is a temporary condition, which commonly develops in childhood. It is characterised by the build-up of fluid behind the eardrum. The condition is non-infective and is usually asymptomatic; however, fluid accumulation may inhibit the transfer of sound and may consequently result in hearing loss. As the level of fluid build-up is not consistent, hearing levels may fluctuate in some cases (Kubba et al, 2011; Whitton & Polley, 2016).

Although more than 50% of OME cases resolve within 3 months, those with OME and hearing loss persisting over 3 months are offered grommets or hearing aid treatment (NICE, 2016). Information and support provided is tailored for families and children who have persistent OME that resolves upon receiving treatment.

Having said this, it is estimated that 30-40% of children have recurrent OME over several years, with only 33% of cases resolving within 2 years (Rosenfeld & Kay, 2003). These children and those wearing hearing aids remain under clinical care until symptoms subside, despite them initially being told that the condition is temporary (NICE, 2016). Additionally, long-term OME may result in further complications such as damage to the eardrum and ongoing infections, which can result in conductive hearing loss (Djordjevic et al., 2015; Maw & Bawden, 1994; Schilder et al., 1999; Paparella, M., Schachern, P. and Cureoglu, 2002; O'Connor et al., 2009). While ENT and Audiology may monitor these children with ongoing OME and related hearing loss, there is no specific information or support provided for these children and their families. These children are who we are classing as having long-term OME and related hearing loss (HL) and who will be the focus of investigation in this research.

In terms of hearing loss related to OME, the reduction of auditory signals during early development may result in a reduced ability to perceive and produce intelligible speech, which is key for spoken communication (Sininger et al, 2010). Furthermore, the fluctuating nature of hearing loss that may accompany OME, may lead to inconsistencies in the auditory signal (Whitton & Polley, 2016). If the hearing loss persists with long-term OME, this may lead to the child having difficulties with communication and social functioning as well as with educational attainment (Brennan-Jones et al, 2014; Su & Chan, 2017).

Prospective longitudinal studies have looked at the impact of OME and HL on cognitive development in early childhood. A key finding across studies is that cognitive and educational outcomes are affected at younger ages, but this impact is diminished or no longer present at later ages in childhood (Bennett & Haggard, 1999; Johnson et al., 2000; Roberts et al., 2002; Hall et al., 2014). On the contrary, studies looking at OME and hearing loss occurring into the teen years have found that outcomes are negatively affected at these ages (Bennett et al, 2001; Augustsson & Engstand). This may indicate that having OME during later childhood and adolescence gives rise to deficits in cognitive and educational development at these later ages. Furthermore, studies have reported that children, adolescents and even young adults with long-term OME and related HL presented with lower scores for social skills and higher levels of internalising behaviours such as anxiety and depression (Gouma et al., 2011; Timmerman et al., 2007; Bidadi et al., 2008; Stenton et al., 2007 & Hogan et al., 2014). This impact on psychosocial behaviour and educational

attainment suggests that there may be an interaction between the two, particularly as the influence has been found during adolescence and beyond.

It is therefore important that we explore the impact that having long-term OME and related HL may have during childhood and adolescence and that we particularly explore how social interaction at school, where children and young people spend a majority of their time, may influence learning.

This detailed exploration can be carried out through qualitative research as quantitative methods will simply state whether there is an association with outcomes, whereas qualitative research can tell us more about the impact (Creswell, 2007). A qualitative study looking at OME in children with cleft palate found that the condition negatively affected their educational and social experiences as well as their emotions (Tierney et al., 2015). This study provides a basis for further exploration of how long-term OME and related HL may influence social interaction and learning experience in childhood and adolescence.

Furthermore, qualitative research is appropriate to explore the support needs of children impacted by long-term OME and related HL. Exploring their support needs is particularly important as these would differ than those of children with more acute and short-lived cases of OME, and as this support is not in place, it is important that we investigate these needs in order to improve service delivery for these children.

This protocol contains information on two related studies, the first of which will seek to explore the impact of long-term OME and related HL on children and adolescents, and second to explore their information and support needs of children and their parents.

2. Theoretical framework

To address the gaps in knowledge, the proposed research described in this protocol will take a qualitative approach to exploring the impact of long-term OME and related HL during childhood and adolescence. The research will take an interpretivist approach using constructivist grounded theory (Urquhart, 2013; Charmaz, 2000). This theoretical perspective relates to discovering knowledge about the world through the social world in which we live in (Braun & Clarke, 2015). Constructivism acknowledges that reality is constructed by those who experience it, and using grounded theory methodology within this approach will allow the researcher to construct an interpretation of participants' lives, living with long-term OME and HL (Mills & Birks, 2014).

In line with Vygotsky's sociocultural theory of cognitive development, which states that children's cognitive development occurs within the framework of social interactions with members of the child's culture, it may be that the two areas of cognitive and social development are linked, particularly as Vygotsky infers that cognitive development is a social process (Vygotsky, 1978). Furthermore, research has shown that social and emotional learning fosters academic learning (Zins et al., 2004). In fact, not only does successful social and emotional behaviour influence success at school but also success in life (Zins et al., 2004). Keeping this in mind, as well as the notion that children with hearing loss generally have difficulties with social and emotional development, it seems of importance to explore this potential impact and understand how we can support children with long-term OME and related HL in overcoming any difficulties they may encounter with success in these areas (Harris, 2014).

This research will particularly explore the social interactive behaviour of children and adolescents with long-term OME and related HL. As most of the child's/adolescent's time is

spent at school, exploring their interactive behaviour here will also help to explore the impact on learning and academic success. Naturalistic data will be obtained in order to describe the social interactive behaviour and engagement at school; and the teachers of the children/adolescents will be interviewed to obtain data that will inform how social behaviour and engagement in the classroom may influence their learning. Furthermore, to gain a perspective on how the condition may affect adolescents at a later stage in life, young adults will be interviewed to tell us about their social behaviour at present. They will also reflect on their past interactive behaviour at school and the emotions associated with this, and how this all may have influenced their career aspirations.

The findings from the research described above are anticipated to inform a second study focusing solely on the information and support needs of children with long-term OME and related HL. We will obtain views from a range of people including young people with or with a history of the condition, parents of children and young people with the condition, and clinicians.

Past qualitative studies conducted in Canada have highlighted that the family is important when considering how to manage living with OME and have identified that the family's relationship with the healthcare system is key (Wuest & Stern, 1990; Wuest, 1991). Hence, it is important that we involve both parents and clinicians in this study to obtain their views and see if this is reflected. Qualitative research is required as it is best suited to understand and grasp the concept of patient's (and families) experiences of living with long-term OME and related HL from multiple perspectives (Creswell, 2007). An exploration of these views may lead to an insight into how families and children with long-term OME and related HL can be better supported.

3. Study objectives and design

3.1 Study aims

The two proposed studies will form core components of a PhD project. The PhD itself aims to investigate the prevalence, impact and support needs of families and children with long-term OME and related HL. While a quantitative analysis of data from a longitudinal population birth cohort study will be carried out to examine the prevalence of long-term OME and HL and its association with developmental outcomes, this qualitative research aims to further explore how the condition may influence development as well as the specific support needs of this group of children and their parents.

Hence, the qualitative research will be split into two linked studies, one focusing specifically on how the condition may affect social interaction and in turn, learning and aspirations upon leaving school; and the second aiming to investigate the support needs of families and children with long-term OME and HL.

Study one

The aim of this study is to explore the social interactions of children and adolescents with long-term OME and related HL and the influence this may have on their educational progress and career path.

Study two

The aim of this study is to explore the information and support needs of families and children with long-term OME and related HL in managing living with the condition.

3.2 Study objectives

Study one

6. To observe and describe the social interactions of children and adolescents with long-term OME and related HL in a school environment.
7. To explore past and present experiences of social interactions of adolescents with long-term OME and related HL.
8. To understand the emotions that children and adolescents with long-term OME and related HL feel when interacting or anticipating interaction with others.
9. To explore how the social behaviour of children and adolescents with long-term OME and related HL at school influences their learning
10. To explore the career choices of adolescents with long-term OME and related HL

Study two

3. To explore how families and children with long-term OME and related HL are supported by services such as the NHS and educational services from the perspectives of parents, clinicians, and affected young people.
4. To explore the information needs and support required by families and children with long-term OME related HL from the perspectives of parents, clinicians, and affected young people.

3.3 Study design

Both qualitative studies will take a grounded theory approach (Strauss & Corbin, 1990). Grounded theory methodology is suitable where there are models available to explain a certain phenomenon but not for the population of interest to the researcher. While we know that the development of children with permanent hearing loss is impacted, here, grounded theory will be used to uncover any impact that long-term OME and related HL may have as well as to put in place a framework of the families and children's support needs. Using this approach will help to access areas that cannot be done with quantitative research, by communicating with those affected and those involved and collecting data from the lives and contexts of the participants (Gordon-Finlayson, 2010).

Study one

The study will explore the social interactions of children and adolescents with long-term OME and related HL and will involve older participants discussing the emotional experiences that underpin their social interactions as well as the paths that their education or career has taken. This will lead to the development of a theory that may explain the impact that long-term OME and related HL has on psychosocial development and will explore how this may potentially influence educational and career paths.

To gain an initial view of the social interactions of children with long-term OME and related HL at school, ethnographic observations and informal interviews will be used to describe the interactive behaviour of the participants. These observations will provide a description of the phenomenon and enable the researcher to build a substantial grounded theory by describing and interpreting their observations within the school culture, which is where most children within the UK spend most of their time (Streubert & Carpenter, 1999).

Children and adolescents with long-term OME and related HL will be observed in their school environment to gain an insight into how the school experience is for them in terms of interaction and their learning experience. Interactions will be observed while the child is in lesson and any after school activities that they take part in. This may allow the researcher to observe the child in both a more educational and a social perspective.

The researcher will interview teachers of the children/adolescents being observed after the child has been observed. This is to gain further insight into the interactive behaviour of the child across a longer period of time and outside of the observation period. This will further inform the researcher's observations. Teachers will also be asked questions regarding their views on the support needs of families and children with long-term OME and related HL.

Interviews with young people who are no longer in school will also take place. These young people may already be working or in further education, so interview questions will cover their social interactive behaviour in the past but also at present. As these participants will be older, the researcher will also be asking questions based on how they got to where they are today.

The data from the observations and interviews will be triangulated. The ethnographic observational methods will provide a rich description of the social interactive behaviour of children and adolescents with long-term OME and related HL, while the interview data will aid not only in describing the phenomena, but also in understanding the impact that long-term OME and related HL may have on social interaction and emotional behaviour. (Aldiabat & Navenec, 2011; Chenitz & Swanson, 1986; Glaser & Strauss, 1967; Hutchinson, 1986).

Procedure	Nov 2019-Feb 2020	Feb 2020	Mar 2020	Apr 2020	May 2020	Jun 2020	Jul 2020	Aug 2020	Sept 2020	Oct 2020	Nov 2020	Dec 2020
Ethics Approval	X											
Approach and recruitment		X	X	X	X	X	X					
Data gathering			X	X	X	X	X	X				
Data analysis			X	X	X	X	X	X	X			
Write up									X	X	X	X

Study two

As there is no set support framework for this group of children, the resulting theory developed from a range of participants' experiences may be used to provide a framework for practice (Gordon-Finlayson, 2010). This will be achieved by having focus group discussions or interviews with young people with long-term OME and related HL, as well as with parents and clinicians of children/adolescents with long-term OME and related HL, to derive a theory from a range of experiences of people who may be involved in supporting these children.

The findings from initial focus groups/interviews will inform further discussions required, the points to be discussed and by whom in order to confirm or refute emerging theoretical themes (Creswell, 2007).

Procedure	Nov 2019-Feb 2020	Feb 2020	Mar 2020	Apr 2020	May 2020	Jun 2020	Jul 2020	Aug 2020	Sept 2020	Oct 2020	Nov 2020	Dec 2020
Ethics Approval	X											
Approach and recruitment		X	X	X	X	X	X					
Data gathering			X	X	X	X	X	X				
Data analysis			X	X	X	X	X	X	X			
Write up									X	X	X	X

4 Methods of data collection

Study one

Observations of children/adolescents at school/college

7-18-year olds with long-term OME and related HL or a history of long-term OME and related HL will be observed by the researcher at their school both in and out of class. We are intending to observe each participant over a period of 2-3 days at their school. This is to observe the child during different time points of the week as well as during different lessons. The researcher will liaise with the school to ensure that the participant will be observed in English and Math's lessons as these are core subjects, and subjects that the participant enjoys the most and enjoys the least. The researcher will ask the participant beforehand when discussing study details and obtaining assent/consent, which are their most and least favourite subjects.

The researcher will observe the participants' participation in these lessons focusing specifically on whether they interact and enter discussions with their peers and teachers or keep to themselves. The researcher will note occurrences of interaction/non-interaction with peers and teachers e.g. if the participant engages in discussion of class work with peers or works on their own, if they engage in class discussions and raise their hand to answer questions, if they approach their teacher for help if needed or if they do not ask for help. This will allow the researcher to describe the general occurrences of interactive behaviour in the classroom for children and adolescents with long-term OME and related HL.

The researcher will also observe the participant outside of the classroom for example, during any after school clubs/activities that they are involved in, if they consent to this. This will hopefully allow observations to be made of interactions in a more social context. The researcher will look to see whether the participant interacts with others during this time or keeps their own company.

During observations, the researcher will take field notes, noting key details. This will include interactive behaviour, the nature of the interactions, class participation, body language and facial expressions. The researcher will also be looking for any hearing difficulties that the child may have e.g. mishearing information and will take note of these and what follows. As the researcher will need to keep focus at all times during observations, scratch notes rather than full field notes may be made. Once observations are complete, the researcher will write up the observations fully, ready for analysis. Although the participant will be observed while amongst others, data will not be collected on any other child other than the participant.

During observations, the researcher will place herself so that she has access to view the participant from the front. As naturalistic data is to be obtained, the researcher will ensure that she positions herself at a distance to the participant so that it is not obvious that she is solely observing them. An observation guide is presented in Appendix I.

Interviews with teachers

At least one teacher for children attending primary school and two of the teachers of the children/adolescents attending secondary school/ sixth form/college who have been

observed will be interviewed by the researcher if they consent. This will be to obtain the teacher's view of the child's interaction in class throughout the time that they have been teaching them and their progress in class but also to ask the teacher's view on the required support needs of children with long-term OME and related HL. These interviews will be semi-structured involving mainly open ended questions and will occur face to face at the end of the school day after the child has been observed, lasting around 15-30 minutes. The researcher will take field notes during the interviews and interviews will be audio-recorded using an encrypted Dictaphone. The standard interview schedule is presented in Appendix II.

Interviews with older adolescents

Face to face, semi-structured interviews will be conducted with 18-24-year olds with long-term OME and related HL. Participants will be asked questions pertaining to their current and past interactions/relations to obtain data which covers a longer period from childhood up until now. Questions regarding their interactions and associated emotions will also be asked to try to identify why participants may or may not interact in a certain way. Questions will mainly be open ended to obtain details. As expressing emotions is a sensitive process, participants will be given the options of responding verbally or using drawing as a way to help express their responses if participants wish to, e.g. drawing figures or mind maps. If the participant is not comfortable with either verbally answering or drawing, they may also write down their response.

Participants will also be asked about their educational attainment throughout life and how content they feel with this as well as their career aspirations. These questions will be asked to gain an insight into whether children with long-term OME and related HL are impacted beyond childhood and throughout life and in order to get a view of how their beliefs about their communication behaviour and educational attainment may influence their career decisions and life goals. This would further highlight the support needs of these individuals. The general interview schedule to be used is presented in Appendix III.

Interviews are anticipated to last between 30 and 60 minutes. Interviews will be audio-recorded using a encrypted Dictaphone. Field notes will also be taken here of facial expressions/body language etc. that cannot be picked up by audio. An interpreter may be present during the interview for Urdu speaking participants.

Study two

Both focus groups and individual interviews will be run by the researcher. Focus groups are the main method of data collection, however due to the uncertainty in numbers of interested young people that we will receive and the wide range in ages for this group, this may be impractical; hence individual interviews may have to be conducted. Furthermore, there is the anticipated difficulty of arranging a suitable time and place for clinicians to all take part in a focus group, therefore clinicians will be individually interviewed. We will however, run a focus group with parents and where possible with the young people. If it is possible to run a focus group with clinicians at their place of work during team meetings, this opportunity will be taken.

Pictor will be used to facilitate the focus group and interview discussions. Pictor is a visual research technique designed to explore the experiences of collaborative working in health and social care contexts (King et al, 2013). The technique involves participants using arrow-shaped adhesive notes or cards to build a representation of the roles and relationships in a particular case. The chart that is produced aids the participant in sharing their experience

and elicits further exploration. It is anticipated that the charts produced by participants will give a representation of where they feel the support for families and children with long-term OME and related HL is needed.

Focus groups

During the focus groups, first each participant will be introduced to the other group members, as they will be discussing views with each other. This will allow them to get more comfortable with each other and ease into discussions. Each participant will be asked to create their own Pictor chart individually. As a rule of thumb, participants will be asked to first use the arrows to represent the current support that they feel is provided for families and children with long-term OME and related HL. They will then be asked to show what support they feel is needed that is not already provided or where more attention is needed. However, this structure of discussion will take place with the first group. The data from the first focus group will be constant comparatively analysed and will inform the structure of the following discussions.

Once participants have completed their individual charts, the researcher and participants will arrange themselves in a circle and the researcher will ask the participants to one by one go through their chart with the group. As each participant goes through their chart, the group will discuss each chart. If participants would like to add or remove any arrows during discussions, they may do so. Each focus group discussion is expected to last approximately 60 to 90 minutes.

The discussions will be audio recorded and the researcher will be taking field notes. The data to be analysed will comprise of the Pictor charts, the recorded data and field notes. Where focus groups will be run with clinicians during their team meetings within their workplace, due to time restraints, they will not be asked to produce a Pictor chart and will directly be asked the questions relating to the support provided and information and support needs.

It is anticipated that many parents may not be able to communicate in English fluently; hence an interpreter will be present for those who speak in Urdu, as this is the most common first language that patients in Birmingham speak. While recruiting and arranging the focus groups, a group specifically for those who speak in Urdu will be arranged.

Another PhD student will be present alongside the researcher to help facilitate focus groups taking place at Aston University. Parents of under 16 year olds will also be present on site.

Interviews

Where interviews are to take place, these will follow the same structure with the participant first creating a Pictor chart and then discussing this with the researcher. The constant comparatively analysed data from the initial focus group and prior interviews will inform the structure of each interview and further questions to be asked, but this will be the general structure. Interviews are expected to last approximately 30-45 minutes.

Discussions and interviews will be audio-taped using an encrypted Dictaphone. The researcher will take field/scratch notes during discussions/interviews, which will aid analysis. Full field notes will then be written up after the focus group discussion has finished.

The initial topic guide for focus group discussions and interviews is presented in Appendix IV.

5 Methods of data analysis

For both studies, scratch notes and field notes taken by the researcher during and after observations, interviews and focus groups will be anonymised at the time of writing. Interviews and focus group discussions will be audio recorded using a digital Dictaphone and then transcribed by the researcher as soon as possible after the interview has finished. The transcribed data will be de-identified and anonymised before analysis. It will be imported into qualitative data software (NVivo) for storage and analysis. Photographs of the Pictor charts from Study 2 will be taken and stored securely. The Pictor charts will be stored in a locked cabinet. All electronic data will be stored on the Aston University secure server, in a password protected electronic folder and will be accessible only by the research team (Aleema Rahman, Dr Amanda Hall, Dr Helen Pryce & Dr Rachel Shaw).

Study one

Analysis will begin from the first point of data collection where the complete field notes for the observations will be descriptively written up by the researcher, from which key themes will be sought out. The transcribed data and field notes from the interviews will be analysed using grounded theory methods of analysis (Straus & Corbin, 1990). The data will be coded first through the process of open coding. The observational data will be triangulated with the interview data from both the older adolescents and teachers, where the themes and codes will undergo axial coding. Here, the themes and codes will be further categorised to identify links between categories. Selective coding will then be used to integrate and refine the categories into a theory. The combination of observational themes and interview data will be analysed through constant comparison where information will be compared to emerging categories (Strauss & Corbin, 1990). Throughout analysis, the researcher will write *memos* – ideas about the emerging theory. This constant comparative process of analysis will feed into subsequent sampling based on the data already collected and will inform further questions to be asked during interview, allowing the testing of emerging ideas until data saturation.

Study two

Grounded theory methods of analysis will be used to analyse the data (Strauss & Corbin, 1990). Analysis will begin from the first point of data collection through constant comparison. The arrows of the Pictor charts will be outlined in black marker and annotations written within the drawn arrows. The researcher will ensure that all annotations are anonymised. While scratch notes will be taken during discussions, analysis of Pictor charts, field notes and audio recordings will begin as soon as possible through open coding where the data will undergo initial categorisation. These codes will be further categorised through axial coding and selective coding to identify links between categories. Throughout analysis, the researcher will write memos– ideas about the emerging theory. If analysis indicates that more data is needed to confirm or refute emerging ideas, theoretical sampling will take place to recruit suitable participants to take part in additionally required focus groups or interviews (Strauss & Corbin, 1990).

After conducting the first focus group, the constant comparison method of analysis will be used when analysing data as this will help to identify emerging themes that may need to be

explored further through subsequent focus groups. This will help to inform the participants that need to be recruited as part of the focus group as well as the structure of discussion for the following groups. If sufficient numbers of participants are not received for a focus group or if there are impracticalities in arranging for the participants to all be at the same place at the same time, then the participants will be interviewed individually.

6 Study setting

Study one

Observations will take place at the participant's school, as this is where 7-18 year olds spend most of their time. Observations of the participant at school will allow observation of their daily interactions. It will also allow exploration of the link with educational outcomes. Observations are anticipated to take place in a classroom on the school playground. The teachers will also be interviewed at the school.

Interviews with the older adolescents will take place either at the participant's home or at an alternatively agreed setting. Interviews have been chosen to take place at the participants' homes not only for their convenience but also as this is where they may feel more comfortable and secure in answering questions relating to their social and emotional behaviour. However, if the participant does not wish to conduct the interview in their home, the interview will be arranged to take place at Aston University or another suitable setting that the participant is comfortable with.

Study two

As participants from different settings will be taking part in the study, focus groups and interviews will take place at different settings depending on the participant. Interviews/focus groups with clinicians will most likely take place within their place of work (hospitals across the West Midlands). Focus groups with young people and parents will take place at Aston University; however, interviews with young people may take place either at Aston University, the participant's home or within the hospital of which they are a patient, if this is possible.

Parents and young people will be recruited from across Birmingham. Aston University is in a convenient location near the Birmingham City Centre so participants should not have too much trouble getting to the study venue. Furthermore, the researcher will be familiar with the venue, which will aid in the smooth running of the study. Where individual interviews are to be run with young people, these may take place after an appointment they have with ENT/Audiology within the hospital, as this will be more convenient for them. Clinicians will be recruited from across the West Midlands; hence, the focus groups/interviews will take place at their place of work, for participant convenience.

7 Sample recruitment

Study one

7.1 Eligibility Criteria

Eligible participants for this study include children and adolescents aged 7-24 years with/with a history of long-term OME and related HL, and teachers of 7-18 year olds with long-term OME and related HL.

7.1.1 *Inclusion criteria*

Children/ Young people

- Male or Female, aged 7-24 years.
- Has long-term OME and related HL which includes:
  - Having OME and conductive hearing loss lasting more than 1 year with or without treatment OR
  - Having recurrent OME and conductive hearing loss over more than 1 year OR
  - Being a hearing aid user for OME related conductive hearing loss OR
  - Having had more than 1 set of grommets or being listed for a second set OR
  - Having conductive hearing loss as a result of complications of long-term OME or treatment of long-term OME
- 7-17year olds must be attending school/sixth form/college (mainstream or specialist)
- 7-17 year olds must be able to communicate in English
- 18-24 year olds must be able to communicate in either English or Urdu
- Informed consent obtained from parents of under 16 year olds
- Living in Birmingham

Teachers

- Teacher of a child/adolescent with long-term OME and related HL who has been observed

7.1.2 *Exclusion criteria*

Children/Young people

- Child under the age of 7 years
- Adult aged 25+ years
- OME and conductive hearing loss present for less than 1 year
- Has sensorineural hearing loss in one or both ears
- 7-17 years old not attending school/sixth form/college
- 7-17 year olds not able to communicate in English
- Informed consent not obtained from parents of over 16 year olds who lack capacity to consent
- Child/adolescent with visual disability (not corrected by lenses)
- Not living in Birmingham or not attending a school in Birmingham

Teachers

- Does not teach any of the children/adolescents with long-term OME and related HL who have been observed

Study two

7.2 Eligibility Criteria

Eligible participants for this study include young people with/with a history of long-term OME and related HL; parents of children/young people with long-term OM related HL, and clinicians.

7.2.1 *Inclusion criteria*

Young people

- Aged ≥13-24 years
- Has long-term OME and related HL which includes:
  - Having OME and conductive hearing loss lasting more than 1 year with or without treatment OR
  - Having recurrent OME and conductive hearing loss over more than 1 year OR
  - Being a hearing aid user for OME and related conductive hearing loss OR
  - Having had more than 1 set of grommets or being listed for a second set OR
  - Having conductive hearing loss as a result of complications of long-term OME or treatment of long-term OME
- Has a history of long-term OME and related conductive hearing loss past the age of 7 years
- Informed consent obtained from parents of under 16 year olds
- Able to communicate in either English or Urdu
- Living in Birmingham

Parents

- Parent/carer of a child/young person aged ≥7-24 years with/with a history of long-term OME and HL
- Able to communicate in English or Urdu
- Living in Birmingham

Clinicians

- Ear, Nose and Throat (ENT) surgeon (who regularly see paediatric patients with OME)
- Audiologists who work with paediatric patients
- Work within the West Midlands

7.2.2 Exclusion criteria

Young people

- Younger than 13 years
- Adult aged 25+ years
- OME and conductive hearing loss present for less than 1 year
- Has sensorineural hearing loss in one or both ears
- Cannot communicate in English or Urdu
- Informed consent not obtained from parents of over 16 year olds who lack capacity to consent Not living in Birmingham

Parents

- Parent/carer of children younger than 7 years
- Parents of children or young people with OME and HL lasting less than 3 months
- Cannot communicate in English or Urdu
- Not living in Birmingham

Clinicians

- Clinician (Audiologist or ENT surgeon) who only works with adults
- Not working within the West Midlands

7.3 Sampling

Study one

Size of sample

While a typical number for sample size cannot be pre-defined, we aim to recruit 20-30 individuals in total to take part in this study in line with the suggested sample size required to develop a well-saturated theory (Creswell, 2007). It is anticipated that there will be more participants for observations, therefore we may recruit around 10-15 children and adolescents for observations and interview 10-15 teachers as well as 5-10 young people.

Sampling technique

Purposive sampling will be used to recruit participants for this study. Participants who are NHS Audiology/ENT patients within Birmingham who are eligible and can contribute to the development of the theory will be recruited (Creswell, 2007). Once data collection has begun and theory ideas have started to emerge, theoretical sampling may be used to recruit individuals who can contribute to the processes of opening and axial coding (Strauss & Corbin, 1990). The process of constant comparison will allow the researcher to identify the type of participant needed to confirm or refute developing theoretical ideas (Creswell, 2007).

Study two

Size of sample

We aim to recruit 25-30 participants in total, including young people, parents and clinicians. We anticipate that within Birmingham alone, there may be a modest number of young people with long-term OME and related HL and we hope to recruit 10-15 young people and parents. There are three hospital trusts within Birmingham itself from which clinicians will be recruited. However, as we are also targeting clinicians working across the West Midlands, we aim to recruit at least 10-20 clinicians.

Sampling technique

We will recruit participants using purposive sampling where the researcher will choose participants who can contribute to the development of the theory (Strauss & Corbin, 1990). The initial focus group to be run will be the one consisting of parents, as it is felt that they may have more to contribute in terms of discussion of support needed for families and children with long-term OME and related HL. The findings of the initial focus group will be used to guide recruitment of participants for the next focus group/interview and so on. This will aid the process of thematic development. If after running the initial focus groups/interviews, more data is required to confirm or refute emerging theoretical ideas, theoretical sampling will be used to recruit further suitable participants who will aid the process of theory development (Strauss & Corbin, 1990). For example, although it has been decided that data will be collected from young people, parents and clinicians, if the analysis process indicates that information is needed from other groups then these individuals will be sought to participate in this study, and if more numbers of participants are required then they will be recruited.

7.4 Recruitment

7.4.1 Sample identification

Study one and Study two

We will be recruiting participants through a number of different routes, which will vary between hospital sites.

Children/Young people & Parents:

Children/young people and parents eligible to take part in this research will be identified through one of the following routes:

1. Invitation and participant information sheets (Appendix V) will be posted out to eligible participants who are patients at University Hospitals Birmingham and Birmingham Children's Hospital. Audiologists at University Hospitals Birmingham (UHB) and Birmingham Children's Hospital (BCH) working under the supervision of Eleanor Cadman (Paediatric Audiology Clinical Lead, UHB) and Rebecca Lawrence (Audiology Manager, BCH) will search their patient databases to identify eligible participants and then post out the information and invitation letter to the identified eligible participants.

2. Audiologists at Heartlands Hospital and Solihull Hospital (UHB) will notify Eleanor Cadman, (Paediatric Audiology Clinical Lead) and Milica Marjanovic (Adult Audiology Team Lead) of eligible participants who are audiology patients. If these patients are due to be seen

for an appointment in clinic, Eleanor and Milica will arrange to book appointments for these patients in the same clinic, on the same day if possible. The researcher has an employment contract with University Hospitals Birmingham as an Audiologist and will arrange to be on site when these clinics are running.

Audiologists/research nurses at Birmingham Children's Hospital will notify Rebecca Lawrence, (Audiology manager) of eligible participants who are audiology patients. If these patients are due to be seen in clinic soon, Rebecca will let the researcher know so that they can arrange to be on site at this time, if possible.

For both sites, the Audiologist who is seeing these patients for their appointment will discuss the research with them (and/or their parents if under 16 years old) and ask if they are interested in hearing more or taking part. If the patient (and parent) is willing, they will be directed to the researcher who will be sitting in a nearby room. The researcher will discuss the study further with the eligible participant and may obtain verbal consent/assent if they are interested in taking part. This applies to the children/adolescents needed for this research. Participation of parents in attendance with 7-15 year olds will also be discussed.

Where parents have not attended with their son/daughter, their son/daughter will be asked to pass on the invitation and participant information sheet to their parent. These sheets will provide the researcher's contact details, should the parent be interested in taking part.

3. Eligible participants may also be ENT patients who are only seen by Audiology for a hearing test before seeing the ENT consultant. Audiologists working on ENT clinics at BCH and Heartlands Hospital/Solihull Hospital (UHB) will be given the inclusion/exclusion criteria so that they can identify any eligible participants from the patients that they see. They will hand out invitation and participant information sheets to eligible participants.

4. Eligible participants who are 16-24 years old (and parents of 16-24 year olds) may also be identified by Konstance Tzifa, Consultant ENT surgeon at University Hospitals Birmingham. She will give eligible participants who attend her clinics the invitation and study information.

Participants identified in clinic will be invited to contact the researcher if they are interested in taking part in this research.

5. ENT and Audiology waiting rooms

Posters advertising the study will be put up in the waiting rooms of these Audiology and ENT departments. Invitation and participant information sheets and posters will be translated into Urdu (the most common first language other than English spoken by patients at UHB). Potential participants will be advised to contact the researcher by email to express their interest in the study or to ask for further information. Posters are presented in Appendix VI.

6. National Deaf Children's Society

The National Deaf Children's Society (NDCS) Birmingham District will also post posters, the invitation and participant information sheet on their Facebook and Twitter social media

pages where interested potential participants will be directed to contact the researcher directly.

Identification of schools & teachers

The schools/colleges of 7-18 year olds who have consented to take part in Study 1 will be contacted by the researcher. The researcher will contact the Head Teacher using a standard letter by email (Appendix VII), informing them of the study and that their student has agreed to participate in the study, asking for permission to conduct the research at their school. The Head Teacher will also be informed that the researcher would like to interview at least two of the student's teachers outside the school day. If the Head Teacher consents to the participant being observed at their school, the researcher will liaise with the Head Teacher to arrange suitable dates and times for the observations to take place. Once this is arranged, the researcher will then ask the Head teacher to pass on the study information to the child's teachers (Appendix V). The teachers who are interested in taking part in the study will be advised to inform the Head Teacher who will then contact the researcher and express interest on their behalf.

As it is anticipated that Head Teachers may take a while to get back to the researcher regarding permission to conduct the observations and interviews with teachers on their school grounds, the researcher will try to identify schools where observations are likely to take place beforehand. The researcher will liaise with clinicians, special educational needs co-ordinators, teachers of the deaf and educational psychologists to communicate with local schools to raise awareness of the research. This communication between the researcher and Head Teachers beforehand may speed up the process of arranging the observations once consent is obtained from the student to be observed.

Clinicians

Clinicians for Study 2 will be recruited as below:

1. NHS Paediatric Audiology departments
    - The Head of Audiology (Rebecca Lawrence) at Birmingham Children's Hospital and Paediatric Clinical lead (Eleanor Cadman) at Heartlands Hospital will distribute the invitation and participant information sheets to their Audiology and ENT colleagues within their department and across the West Midlands (Appendix V).

Individual clinicians who are interested in taking part in the study will be invited to email the researcher expressing their interest. Clinicians who have a managing role will be advised to inform the researcher if they are willing to have their team take part in a focus group. The manager however, will discuss the study with their team before the focus group takes place and only those who consent to taking part in the study will take part in the discussion.

All potential participants for both studies who contact the researcher and express their interest in taking part in the study will be asked baseline-screening questions (Appendix VIII)

by the researcher to confirm that they are eligible to take part in the study. If the criteria is met, the study will be further discussed and consent will be obtained.

Children, young people, and parent participants will be offered a £10 shopping voucher as a thank you for them taking part in this study, whereas professionals will not. Expenses for travel to Aston University however, will be reimbursed for all participants.

7.4.2 Consent

Study one and two

Before obtaining consent/assent, the researcher will ensure that potential participants have full awareness of the purpose of the project, the procedures, analysis, data storage and potential outputs and will have the opportunity to ask questions. They will be made aware that:

- Anonymity will be protected through assigning aliases and patient identification numbers
- Confidentiality will be maintained throughout by the researcher, with the exception of the unlikely situation where the researcher may find themselves in a *duty of care* position
- Although all participants will sign a confidentiality agreement, confidentiality on behalf of the other participants in focus groups cannot be guaranteed.

The researcher will confirm that the potential participant meets the eligibility criteria and is suitable for the study.

Study one

Children aged 7-15 years

Parents who are willing for their child to take part in this study will email the researcher to inform them of their interest. The researcher will provide further information on the study and answer any questions. A meeting with the child and their parents will be arranged – this will take place either at the potential participant's home or at Aston University. At this meeting, informed written consent will be obtained from the parent for their child to take part in an observation and written assent will be obtained from the child.

Participants who have been seen in clinic and recruited will provide verbal assent during this meeting in clinic and parents will provide informed written consent. If consent or assent is not obtained at this point as the potential participant and their parent would like more time to make a decision, they will be asked to contact the researcher by email to express their interest if they decide later that they would like to take part. Verbal assent from the child and informed written consent from their parent will then be obtained in a meeting as described above.

The child's assent will be monitored across the observation period. They will be told to inform their teacher if they no longer want to be part of the study who will then inform the researcher.

Adolescents aged 16-18 years

Initially, informed verbal consent will be obtained from these participants who are to be observed when they have contacted the researcher to express their interest. The researcher will arrange a suitable time and place to obtain informed written consent from the participant prior to observations taking place. Consent will be monitored across the observation period and participants will be informed to let their teacher know if they no longer wish to take part in the study. The teacher will then inform the researcher.

Consent/assent will not be obtained from the participant's classmates and classmates parents as the researcher is only interested in observing the participant and will only be collecting data on them and not on their classmates.

Young people (18-24 year olds)

Initially, informed verbal consent will be obtained from participants when they have contacted the researcher to express their interest. Written consent will be obtained on the day of the interview, prior to starting the interview.

Young people aged 16+ with a learning difficulty

Informed consent will still need to be obtained if the eligible participant is aged 16 and above and may lack capacity to consent due to a learning disability. Capacity to consent will be assessed through the eligible participant's medical record when initially being identified as an eligible participant. Consent will be monitored across the study period for as long as the participant is taking part.

Teachers

Teachers will express their interest in taking part in the study by informing the Head teacher of the school that they work out who will then contact the researcher to let them know. Prior to conducting the interview with the teacher, written informed consent will be obtained on that day.

Study two

Adolescents aged 13-15 years

Parents who are willing for their child to take part in this study will email the researcher to inform them of their interest. The researcher will provide further information on the study and answer any questions. A meeting with the child and their parents will be arranged – this will take place either at the potential participant's home or at Aston University. At this meeting, informed verbal consent will be obtained from the parent for their child to take part in an interview/focus group and verbal assent will be obtained from the child.

Participants who are seen in clinic will provide verbal assent during this meeting in clinic and parents will provide informed verbal consent. If consent or assent is not obtained at this point as the potential participant and their parent would like more time to make a decision, they will be asked to contact the researcher by email to express their interest if they decide later

that they would like to take part. Verbal assent from the child and informed verbal consent from their parent will then be obtained in a meeting as described above.

Parents will accompany their child to Aston University where the focus group will take place. Interviews may also take place here. If interviews are to be conducted in the participant's home, their parent will also be present. This means that informed written consent can be obtained face to face from the parent on the day of the focus group/interview, prior to this taking place. Verbal assent will be obtained again face to face from the child at this point to confirm that they are still willing to take part in the research.

Participants aged 16+ (parents and young people)

Initially, informed verbal consent will be obtained from participants when they have contacted the researcher to express their interest. Written consent will be obtained face to face, on the day of the focus group/interview, prior to starting the discussion/interview.

Young people aged 16+ with a learning difficulty

Informed consent will still need to be obtained if the eligible participant is aged 16 and above and may lack capacity to consent due to a learning disability. Capacity to consent will be assessed through the eligible participant's medical record when initially being identified as an eligible participant. Consent will be monitored across the study period for as long as the participant is taking part.

Clinicians

Clinicians who are Head of department that are contacted will contact the researcher expressing their interest for their team to take part in the study and collective verbal consent will be obtained from this Manager on part of their team. The researcher will be attending the team meeting where the focus group will be taking place and present the study information first, so all clinicians can make an informed decision as to whether they would like to take part in the study. Informed written consent will be obtained from each clinician before proceeding with the focus group discussion on the day that the discussion takes place.

Where it is not possible to run a focus group, individual clinicians who have received the invitation and study information and who are interested in taking part in the study will contact the researcher to express their interest and to arrange a suitable date and time for an interview to take place. Informed written consent will be obtained on the day of the interview, prior to starting the interview.

Consent forms for all groups or participants are presented in Appendix IX.

8. Assessment of Safety

8.1 Participant Safety

Study one

Risks are limited with this study with observational and interview methods being used. However, the actual burden of being observed is present. To ensure that the participant does not feel as though it is solely them being observed, the researcher will seek to be as

naturalistic as can be. Participants will be observed whilst being amongst others and the researcher will keep their distance where possible so it is as they are in the background.

A burden that may be present for young people being interviewed is any psychological distress resulting from discussion of sensitive topics such as emotions, socialisation and educational attainment. The researcher will ensure that the participant is willing to address these questions prior to starting the interview. If the participant objects to answering these questions, the interview will not take place. If the participant is happy to continue with the interview, the researcher will be cautious, keeping any signs out for discomfort or distress. If the participant becomes distressed, the researcher will pause the interview and give the participant a few minutes. The researcher will ask the participant if they are happy to continue or would like the stop the interview and will make it clear that the interview can be stopped at any point if the participant does not feel like they can continue or if they would like to withdraw from the study. The researcher will identify any participants with particular distress and suggest onward referral if necessary according to local protocols.

Any issues revealed during the study regarding participants and safeguarding will be reported to the relevant parties according to local protocols. Issues which may be raised during school observations will be reported to the school Head Teacher.

All participant data will be anonymised and kept confidential unless needs to be disclosed if participant safety is threatened.

Study two

The procedures of this study do not put participants at any particular risk. Risk assessment of the setting where focus groups/interviews will be taking place at Aston University will be carried out beforehand by the researcher.

13-15 year olds will need to be accompanied to the focus group or interview by their parent/guardian. If interviews are to be conducted in the participant home, parents will have to be home at time of interview. Parents can either be present in the same room during interview or not, depending on participant preference. Where focus groups/interviews are to be conducted at Aston University, parents must accompany their child to the site. The focus groups/interviews will take place within a large audiology teaching space suitable for focus group discussions within the Audiology department. Victoria Olaniyan Funmi (PhD student) will also be present alongside the researcher during focus group discussions to ensure smooth running of the focus groups.

A burden that may be present for participants is any psychological distress, particularly for the young people and parents resulting from discussion of the sensitive topic of managing to live with long-term OME and related HL. The researcher will ensure that the participant is willing to take part in these discussions prior to starting. If the participant is happy to continue with the discussion, the researcher will be cautious, keeping any signs out for discomfort or distress. If the participant becomes distressed, the researcher will pause the discussion and the participant may leave the room to have a few minutes to themselves. The researcher will stay in the room with the rest of the participants while Victoria will accompany and see to the participant when they leave the room. Victoria will ask the participant if they are happy to continue or if they would like to withdraw from the discussion. Although participants will be informed beforehand that they are free to withdraw from the study at any point, Victoria will remind the participant that they can withdraw from the discussion at any point if they do not feel as though they can continue. Participants with particular distress will

be identified and the researcher will (notify their parents/guardian for participants 13-18 years old and) make onward referrals according to local protocols.

Any issues revealed during the study regarding participants and safeguarding will be reported to the relevant parties according to local protocols.

Participants may not be comfortable discussing issues with strangers in focus groups, particularly the young people and parents as this will be personal to them. However, they will be introduced to each other and made aware that they all share the common experience of living with long-term OME and related HL. Parents attending the focus groups with their child will also be asked to keep discussions confidential.

All participant data will be anonymised and kept confidential unless needs to be disclosed if participant safety is threatened. As participants will be interacting with others during focus group discussions, all participants will sign a confidentiality agreement. Participants will be given the right to withdraw at any point of study.

8.2 Researcher safety

Study one

In the case of lone working, interviewing participants in their home, the researcher will abide by the Aston University Lone working policy and ensure that they have frequent contact with the other members of the research team by phone who will know where she is at all times. Where possible, the researcher will be accompanied by another researcher to reduce the risk of lone working.

Study two

The researcher will be familiar with the premises of the focus group discussions taking place at Aston University (and interviews if taking place at Aston University) will be taking place at their place of work. The rest of the research team will be aware of the running of these focus groups discussion and contact will be kept with them. Furthermore, the researcher will have assistance with the running of the focus groups from another PhD student at Aston University.

If interviews are to be conducted in the participants' homes, the researcher will abide by the Aston University Lone working policy. Where possible, the researcher will be accompanied by another researcher to reduce the risk of lone working.

8.3 Procedures for Reporting Adverse Events

Any adverse events associated with the specific procedures will be formally reported to the Aston University Research Ethics Committee, NHS REC and the Trust R&D Office.

9. Ethics and Governance

The two studies will be conducted in compliance with principles of the Declaration of Helsinki (1996), the principles of GCP and in accordance with all applicable requirements including but not limited to the Research Governance Framework and any subsequent amendments.

This protocol and related documents will be submitted for review to a National Research Ethics Service Research Ethics Committee (NRES REC).

The Chief Investigator will submit an annual and a final report to the REC on behalf of the Sponsor. Governance approvals will be sought from Aston University.

10. Quality Assurance

Monitoring and auditing of this study will be in accordance with the Aston University Monitoring and Auditing Policy for Human Participant Research as well as NHS quality assurance processes.

11. Data Management

The Chief Investigator will act as custodian of the study data.

The following guidelines will be strictly adhered to:

- Participant data will be anonymised
- All study data will be stored securely in accordance with University or Trust data storage policies for research data

Study data will be archived in accordance with Aston University Archive Policies and Procedures for archiving of clinical research data.

12. Publication

It is intended that the results of the study will be reported in a student doctoral thesis and may be disseminated at conferences and in peer reviewed scientific journals.

13. Insurance/Indemnity

Aston University will provide indemnity/insurance for the design and management of the research.

14. Signature of Chief Investigator

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Chief Investigator	**Date**
Name of Chief Investigator	

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Appendices

Appendix I

Observation guide for classroom observation

Setting of the room/environment (sketch)

	Details: Where? When? How many times? Etc.	Notes e.g. body language, facial expressions
Position of participant in this setting		
Participant at start of lesson/activity – do they seem excited? Neutral? Are they ready for class? Did they arrive on time?		
Is participant engaged? Paying attention? Taking part in discussions, volunteering to answer questions? Asking for help?		
Is participant withdrawn? Un-interactive?		

Does it seem as though participant knows/does not know what is going on?		
Is participant inattentive? Distracted? Is participant always focused on work? Interfering with peers work?		
Participant talking with classmates too much? (chit-chat)		

Is participant making an effort to complete class tasks? Need encouragement?		
Any misunderstandings/issues due to hearing difficulty?		
Participant at end of lesson? Packing up/leaving early? Chatting away? Staying behind to finish work?		
How long are any interactions?		

Overall notes – key points:

Observation guide for After school activity

Setting of the room/environment (sketch)

	Details: Where? When? How many times? Etc.	Notes e.g. body language, facial expressions
Position of participant in this setting		
What kind of activities is participant involved with?		
Indoors? Outdoors?		

Who is participant with? Alone? Peers? Teachers? Same class? Different year?		
How long are any interactions?		
If with others, what role does participant play in group?		
Indoors? Outdoors?		

What is behaviour like? Active? Withdrawn?		
Is participant more interactive than in class?		

Any misunderstandings/issues due to hearing difficulty?		
Do they seem like they are enjoying themselves? **How are they at the start/end of period?**		

Overall notes – key points:

Appendix II

Interview guide (Teachers)

Class interaction

- *Tell me about [student's] usual interaction in class.*
  With classmates, you, engagement in class.

    - Cause any disruption to the class? Withdrawn? Need encouraging?

- *Can you tell me whether you think they work better individually or in a group?*
- *How is the student when presenting class presentations?*

Influence on learning/attainment

- *Can you tell me about [student's] progress in your class?*
- *Do you think that their interactive behaviour in class influences their learning? How so? Examples.*

Out of class interaction

- *Can you tell me, from what you have seen, how [student's] interactive behaviour is outside of the classroom? E.g. during breaks, after school clubs.*

Support needs

Now some questions on the more general support needs of children with long-term glue ear and related hearing loss.

- *Are there any areas in particular, where you feel, from what you know and your experience, that children with the condition need any or would benefit from any specific support?*

    - Do you think there is anything that the child's family needs to do to support them?

- *And what about the family themselves, are there any areas where you feel they need support in order to help the child to manage living with the condition?*
- *Can schools do anything to help either the child or family?*

Appendix III

Interview guide (18-24 year olds)

Social behaviour

- *Do you feel that your hearing difficulties influence your social interactive behaviour? Can you describe how?*

    - How often do you communicate with friends/family?
    - How do you communicate with them? Face to face? Phone?

Daily interactions

- *Can you describe how your day-to-day interactions are affected by your hearing loss? E.g. with colleagues/teachers, shopping, commuting etc.*

Initiating and engaging in conversation

- *How do you feel about initiating conversations?*
- *How do you feel about engaging in conversation?*

Feelings about interaction

- *Can you describe how you generally feel when you have to interact with others? What goes through your head at the start, during and at the end of the interaction?*

Interaction at school

- *Can you tell me about how your hearing loss might have affected your social interactions when you were at school?*

    - Engagement in class, asking for help
    - Did you prefer to work with others or by yourself? Why is this?
    - What did you do at break and lunch times?
    - Were you part of any clubs or did you take part in any after school activities?
    - Are you still in touch with your school friends?

Impact on education

- *Do you feel that your interactive behaviour at school affected your learning or how well you did at school? How so?*

Career

- *Tell me about your future career plans*

    - Currently studying/working?
    - Preferred Job roles – in a team, independent, leader, own boss?

Appendix IV

Study 2 Topic guide

Parents

- *What support are you getting to help you, your child and family manage living with long-term OME and hearing loss?*
    - From all round – NHS, School, other services

- *What support do you feel is needed for you, your child and family, that is not there or is lacking, to help you manage with living with the condition?*
    - From all round – NHS, School, other services

- *How do you feel that families can support the child better in managing to live with the condition?*

Children

- *What support do you get as a child with long-term OME and related hearing loss?*
    - From all round – NHS, School, other services

- *What support do you feel is needed for you to manage better with your condition?*
    - From all round – NHS, School, other services

- *How can your family better support you in managing to live with the condition?*

Clinicians

- *How do you support families and children with long-term OME and hearing loss in managing the condition?*

- *How do you think families and children with long-term OME and hearing loss can be better supported by yourselves and other services?*
    - From all round – NHS, School, other services

- *How do you feel that the family itself can support the child better in managing to live with the condition?*

Appendix V

Participant information sheets

Aston University

Site or Collaborator Logo(s)
(to be added)

Participant Information Sheet

Invitation

We would like to invite you to take part in a research study.

Read this leaflet carefully, and talk about it with your parents/whoever looks after you.

If you have any questions, you can ask your parents to ask us. We will be happy to answer your questions.

What is research?

Research is when you collect information to answer questions. We do this to understand and solve problems.

Why are we doing this research?

We want to understand what school is like for children with hearing loss, like you. This will help us to see how we can make school better for you.

Why have I been chosen?

We would like you to take part in this study because you have hearing loss and you go to school, so we would like to see what school is like for you.

What will happen to me if I take part?

If you want to take part in this study, we will come to your school for a few days to see what it

is like for you. We will see what school is like for you when you are in your lessons and when you are at any clubs after school.

Will taking part help me?

This study will not help you right now but you will be helping us to find out ways that we can help you and other children with hearing loss at school.

Will anything about the research upset me?

Taking part in this study shouldn't upset you but if you do get upset just let us know and you don't have to carry on.

Do I have to take part?

No. It is up to you and whoever looks after you to decide if you would like to take part and you can always change your mind.

If you don't want to take part in the research anymore at any time, you can tell your parents or your teacher. They will not be cross with you.

Will anyone else know that I am taking part?

Only your parents, teachers and anybody that you tell yourself will know that you are taking part. We will not tell anybody else.

What will be done with the information I give you by taking part in this study?

We will be taking notes when we are at your school. Then we will type up the notes and they might get published in special magazines called scientific journals.

What happens next?

If you want to take part in this research, ask your parents to let the research team know. The researcher will then contact you and you parents to tell you more and you can ask any more questions.

Research Team

Name	**Email address**
Aleema Rahman	rahmana9@aston.ac.uk
Dr. Amanda Hall	a.hall@aston.ac.uk
Dr. Helen Pryce	h.pryce-cazalet@aston.ac.uk

Thank you for taking time to read this information sheet. If you have any questions about the study, please ask your parents to email us and we will

Aston University

Site or Collaborator Logo(s)

(to be added)

Participant Information Sheet

Invitation

We would like to invite you to take part in a research study.

Before you decide if you would like to join in, take time to read this leaflet carefully, and discuss it with your parents/who ever looks after you.

If something doesn't make sense or you have more questions, you can ask your parents to ask us. Our details can be found at the end of this leaflet. We will be happy to answer your questions.

Why are we doing this research?

This research is being done to understand what school is like for children with hearing loss, like you. This will help us to see how we can improve your time at school to support you better.

Why have I been chosen?

You are being invited to take part in this study because you have hearing loss and you are a school student, so we would like to see what school is like for you.

What will happen to me if I take part?

Taking part in this study means that we will come to your school for a few days. The researcher will sit in your lessons and any after school activities/clubs that you are part of. This is to see what school is like for you as a child with hearing loss.

What will be done with the information I give you by taking part in this study?

If it's OK with you, we will be taking notes when we are at your school. Then we will type up the notes and they might get published in special magazines called scientific journals.

What about my personal information?

We will make sure that your personal information like your name and contact details are kept private.

Do I have to take part?

No. It is up to you and your parents/guardian to decide whether or not you wish to take part.

If you do decide to participate, you would still be able to change your mind if you don't want to take part in the research anymore at any time, just tell your parents or your teacher. They will not be cross with you.

Will anyone else know that I am taking part?

Only your parents, teachers and anybody that you tell yourself will know that you are taking part. We will not tell anybody else and will keep all of your information confidential. This means that we will label your information with a code rather than with your name or any other of your details.

Will taking part help me?

Taking part in this study will not help you right now. However, it will help us to find out ways that we can help you and other children with hearing loss at school in the future. You will get a £10 shopping voucher as a thank you for helping us.

Will anything about the research upset me?

Taking part in this study shouldn't upset you but if you do get upset just let us know and you don't have to carry on.

Did anyone else check that the research is okay?

The research has been checked that it is fair by a group of people called the Research Ethics Committee.

What happens next?

If you agree to take part in this research, ask your parents to let the research team know. The researcher will then contact you and you parents to tell you more and you can ask any more questions.

Research Team

Name	Email address
Aleema Rahman	rahmana9@aston.ac.uk
Dr. Amanda Hall	a.hall@aston.ac.uk

Dr. Helen Pryce	h.pryce-cazalet@aston.ac.uk

Thank you for taking time to read this information sheet. If you have any questions regarding the study please ask your parents to email us and we will be happy to answer them.

Aston University

Site or Collaborator Logo(s)

(to be added)

Exploring the impact of long-term glue ear and related hearing loss on children and adolescents and their information and support needs

Participant Information Sheet

Invitation

We would like to invite you and your parents to take part in a research study.

Before you decide if you would like to join in, take time to read this leaflet carefully, and discuss it with your parents.

If something is not clear or you have more questions, you can contact us or ask your parents to contact us. Our details can be found at the end of this leaflet. We will be happy to answer your questions.

Why are we doing this research?

This research is being done to find out how we can help children and young people with long-term glue ear and hearing loss, like you. We want to find out how we can make it better for you and your families to manage living with your glue ear and hearing loss.

Why have I been invited to take part?

You are being invited to take part in this study because you have long-term glue ear and hearing loss. We would like to talk to you, your parents, and other children with long-term glue ear and hearing loss and their parents as well as see what school is like for you.

What will happen to me if I take part?

There are two parts to this research that you can take part in. The first part involves the researcher coming to your school and observing what school is like for you while you are in lessons and any after school club/activity that you are part of. You won't have to do anything other than go to school

like you normally do, the researcher will just be sitting in your classroom away from you and taking notes if that's okay with you.

The second part involves you taking part in a group discussion with other young people with long-term glue ear and hearing loss. Your parents will be part of a different group with other parents. This should last about 1 hour. The discussion will be about the support you feel is needed for families and children with long-term glue ear and hearing loss like you.

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part.

You can take part in both parts of the research: 1) School observation 2) Focus group) or just one if you would prefer that. If you do decide to participate, your parents will need to sign a consent form. Even if you decide to take part, you would still be able to change your mind if you do not want to take part anymore.

What will happen to the information recorded from the observations and given during the group discussion?

If it's OK with you, we will be taking notes during the school observations which will be typed up fully once the observations are complete. The observations will not be video recorded or audio recorded.

During the group discussion/interview if it is OK with you and the other group members, when we talk to you, we will audio record the conversation.

The recording of the discussion will be typed into a document by the main researcher and any names that have been used will be replaced with a code to keep you anonymous.

The recordings will be deleted as soon as the discussion has been typed up and checked.

If you agree to take part in the group discussion we cannot promise that what you say will be kept within the group, but all participants will be asked not to discuss what has been spoken about during the group at the start of the focus group.

Will anyone else know that I am taking part?

Only your parents and anybody that you tell yourself will know that you are taking part. At school, only the teachers of the lessons that will be observed will know. We will not tell anybody and will keep all of your information confidential. This means that we will label your information with a code rather than with your name or any other of your details.

The data we collect will be stored securely.

Will taking part in this study help me?

Taking part in this study will not help you right now. However, it will help us to find out ways that we can help you and other children and your families manage living with long-term glue ear and hearing loss in the future.

Will taking part in this study harm me?

Taking part in this study should not be harmful but if you do get upset just let us know and you will not have to carry on if you do not want to.

What happens if I tell you something that concerns you about my health or welfare?

In the unlikely event of this happening, we will discuss with you how this should be addressed and will notify your parents. If necessary, to protect you, we will report your concern to the appropriate person or bodies.

Expenses and payments

We will pay you back your expenses for travel to Aston University, which is where the focus group discussion will take place. We will provide snacks and drinks that you are welcome to have during the focus group discussion.

We will also give you a £10 shopping voucher as a thank you for taking part in the study.

Did anyone else check that the research is okay?

The research has been checked that it is fair by a group of people called the Research Ethics Committee.

What if I have a concern about my participation in the study?

If you have any concerns about participation in this study, speak with your parents and ask them to speak to the research team who will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being carried out your parents should contact the Aston University Director of Governance, Mr. John Walter, j.g.walter@aston.ac.uk or telephone 0121 204 4869.

What happens next?

If you agree to take part in this research, ask your parents to let the research team know. The researcher will then contact you and you parents to tell you more and you can ask any further questions.

Research Team

Name	Email address
Aleema Rahman	rahmana9@aston.ac.uk
Dr. Amanda Hall	a.hall@aston.ac.uk
Dr. Helen Pryce	h.pryce-cazalet@aston.ac.uk

Thank you for taking time to read this information sheet. If you have any questions regarding the study please don't hesitate to ask one of the research team.

Aston University

Site or Collaborator Logo(s)

(to be added)

A qualitative exploration of the impact of long-term glue ear and related hearing loss on children and adolescents and their information and support needs

Participant Information Sheet

Invitation

We would like to invite you to take part in a research study.

Before you decide if you would like to participate, take time to read the following information carefully, and if you wish, discuss it with others, such as your family, friends or colleagues.

Please ask a member of the research team whose contact details can be found at the end of this information sheet if there is anything that is not clear, or if you would like more information before you make your decision.

What is the purpose of the study?

This study aims to understand what school/college is like for children and adolescents with long-term glue ear and related hearing loss. This will help us to understand any effect that having long-term glue ear and related hearing loss in childhood/adolescence has on educational experience and how this may influence educational outcomes. This will then enable us to identify the relevant support that is needed both within schools and out of school for this group of children/adolescents. We also aim to explore the general support needs of families and children with long-term glue ear and related hearing loss.

Why have I been chosen?

You are being invited to take part in this study because you are a school/college student and you meet the criteria for participation in this study which includes having long-term hearing loss related to glue ear.

What will happen to me if I take part?

There are two parts of this research that you can take part in:

Part 1

This involves you being observed at your school/college for up to 3 days. This is to see what the school/college environment and experience is like for you as an adolescent with long-term glue ear and related hearing loss. You won't have to do anything other than go to school/college like you normally do. The researcher will be sat in the classroom during your lessons and any after school clubs/activities that you are part of, and will be taking notes if that is okay with you.

Part 2

This involves taking part in a focus group discussion with other young people with long-term glue ear and related hearing loss. The discussion will be centered around what support is currently provided for families and children with long-term glue ear and related hearing loss and what further support is needed.

The main researcher will be present to facilitate the group and will be taking notes during discussions. Overall, this should take around 60-90 minutes.

What will happen to the information recorded from the observations and given during the group discussion?

If it's OK with you, we will be taking notes during observations which will be typed up fully once the observations are complete. The observations will not be video recorded or audio recorded.

During the group discussion/interview if it is OK with you and the other group members, when we talk to you, we will audio record the conversation.

The recording of the discussion will be typed into a document by the main researcher and any names that have been used will be replaced with a code.

The recordings will be destroyed as soon as the discussion has been typed up and checked.

This information that you provide might be included in the reporting of the research study, but will be anonymous so nobody will know that it is from you.

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part.

You can take part in both parts of the research: 1) School/college observation 2) Focus group or just one if you would prefer that. If you do decide to participate, you will need to sign a consent form. You would still be free to withdraw from the study at any time without giving a reason if you change your mind.

Will my taking part in this study be kept confidential?

Yes. A code will be attached to all the data you provide to maintain confidentiality.

Your personal data (name and contact details) will only be used if the researchers need to contact you to arrange study visits or collect data by phone. Analysis of your data will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

To ensure the quality of the research the study Sponsor may need to access your data to check that the data has been recorded accurately. If this is required, your personal data will be treated as confidential by the individuals accessing your data.

If you agree to take part in a focus group we cannot promise that what you say will be kept within the group, but all participants will be asked not to discuss what has been spoken about during the group at the start of the focus group.

What are the possible benefits of taking part?

While there are no direct benefits to you of taking part in this study, the data gained will inform us of how long-term glue ear and related hearing loss may affect children and adolescents in terms of their learning at school/college and the experience on a whole. This will all feed in to informing support frameworks for these children and adolescents. You will be helping to potentially improve services for children who have long-term glue ear and hearing loss and for their families.

What are the possible risks and burdens of taking part?

While the risks of this research are minimal, the risk of you potentially experiencing distress may be present when discussing support needs if any sensitive information is discussed. Although this risk is minimal, if you do become distressed, the discussion will be stopped and you will only need to continue to participate if you wish.

What happens if I tell you something that concerns you about my health or welfare?

In the unlikely event of this happening, we will discuss with you how this should be addressed. If necessary, to protect you, we will report your concern to the appropriate person or bodies.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. If the results of the study are published, your identity will remain confidential.

A lay summary of the results of the study will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

The results of the study will also be used in *Aleema Rahman's PhD* thesis.

Expenses and payments

The focus group will take place at Aston University. Travel to Aston University will need to be arranged and expenses for your travel can be reimbursed.

You will receive a £10 shopping voucher as a thank you for your participation.

Who is funding the research? Who is organising this study and acting as data controller for the study?

Aston University is organising and funding this study and acting as data controller for the study.

How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your:

- Name/initials - NHS number - Contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

What are my choices about how my information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can I find out more about how my information is used?

You can find out more about how we use your information

- At www.hra.nhs.uk/information-about-patients/
- Our webpage available at **www.aston.ac.uk/dataprotection**
- By asking one of the research team, or
- By sending an email to **dp_officer@aston.ac.uk**

Who has reviewed the study?

This study was given a favorable ethical opinion by the West Midlands - Edgbaston Research Ethics Committee.

What if I have a concern about my participation in the study?

If you have any concerns about your participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Director of Governance, Mr. John Walter, j.g.walter@aston.ac.uk or telephone 0121 204 4869.

What happens next?

If you would like to take part in this research, please get in touch with the research team to let them know. The researcher will then contact you to tell you more and you will have the chance to ask any further questions.

Research Team

Name	Email address
Aleema Rahman	rahmana9@aston.ac.uk
Dr. Amanda Hall	a.hall@aston.ac.uk
Dr. Helen Pryce	h.pryce-cazalet@aston.ac.uk

Thank you for taking time to read this information sheet. If you have any questions regarding the study, please do not hesitate to ask one of the research team.

Aston University

Site or Collaborator Logo(s)

(to be added)

A qualitative exploration of the impact of long-term glue ear and related hearing loss on children and adolescents and their information and support needs

Participant Information Sheet

Invitation

We would like to invite you to take part in a research study.

Before you decide if you would like to participate take time to read the following information carefully, and if you wish discuss it with others, such as your family, friends or colleagues.

Please ask a member of the research team whose contact details can be found at the end of this information sheet if there is anything that is not clear, or if you would like more information before you make your decision.

What is the purpose of the study?

By conducting this research we aim to:

- Explore past and present experiences of social interactions of young people with long-term glue ear and related hearing loss
- Understand the emotions that children and young people feel when communicating
- Explore how this may affect education and career choice
- Identify the more general information and support needs of families and children with long-term glue ear and related hearing loss

This will help us to understand any effect that having long-term glue ear and related hearing loss in childhood/adolescence has on social ability and how this may influence learning and educational outcomes. We may also see overall how this may affect self-esteem and future aspirations. This will then enable us to identify the relevant support that is needed both within schools and out of school for this group of children/adolescents.

Why have I been chosen?

You are being invited to take part in this study because you meet the criteria for participation in this study, which includes:

- Having glue ear and conductive hearing loss lasting more than 1 year with or without treatment OR
- Having recurrent glue ear and conductive hearing loss over more than 1 year OR
- Being a hearing aid user for glue ear related conductive hearing loss OR
- Having had more than 1 set of grommets or being listed for a second set OR

- Having conductive hearing loss as a result of complications of long-term glue ear or treatment of long-term glue ear

What will happen to me if I take part?

There are two components to this research:

Part 1

This involves you being interviewed for approximately 30-60 minutes. Questions asked will revolve around your past and present social interactions and the emotions which underpin these. You will also be asked questions based on your educational outcomes throughout life and career choice and aspirations.

Interviews will either take place in your home, at Aston University or an alternative agreed setting depending on your preference.

Part 2

This involves taking part in a focus group discussion with other young people with long-term glue ear and related hearing loss. The discussion will be centered around what support is currently provided for families and children with long-term glue ear and related hearing loss and what further support is needed.

The main researcher will be present to facilitate the group and will be taking notes during discussions. Overall, this should take around 60-90 minutes. Focus group discussions will take place at Aston University.

How will the conversations that take place during the interview and focus group be recorded and the information I provide managed?

If it's OK with you (and other group members for focus groups), when we talk to you, we will audio record the conversation.

The recording will be typed into a document (transcribed) by the main researcher. During the transcription process any names that have been used will be replaced with a pseudonym.

Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy.

Any extracts from the interview/focus group discussion that are included in the reporting of the study will be anonymous.

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part.

You can take part in both parts of the research 1). Interview on social interactions 2) Focus group/interview on support needs or just one if that is what you would prefer. If you do decide to participate, you will be asked to sign and date a consent form. You would still be free to withdraw from the study at any time without giving a reason.

Will my taking part in this study be kept confidential?

Yes. A code will be attached to all the data you provide to maintain confidentiality.

Your personal data (name and contact details) will only be used if the researchers need to contact you to arrange study visits or collect data by phone. Analysis of your data will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

To ensure the quality of the research the study Sponsor may need to access your data to check that the data has been recorded accurately. If this is required your personal data will be treated as confidential by the individuals accessing your data.

If you agree to take part in a focus group, full confidentiality cannot be guaranteed on behalf of the other focus group participants (as we cannot control who they talk to or what they say after the discussion). However, all participants will be asked to maintain confidentiality at the start of the focus group.

What are the possible benefits of taking part?

While there are no direct benefits to you of taking part in this study, the data gained will inform us of how long-term glue ear and related hearing loss may affect children and adolescents in terms of their social interactions and emotional well-being as well as how this affects their learning at school and career aspirations. This will all feed in to informing support frameworks for these children and adolescents. You will be helping to potentially improve services for children who have long-term glue ear and hearing loss and for their families.

What are the possible risks and burdens of taking part?

While the risks of this study are minimal, there is the risk of you potentially becoming distressed when discussing social interactions and the sensitive topic of emotions as well as support needs. We will get your consent prior to starting the interview/focus group and you will not be forced to answer questions. If you do become distressed during the interview/focus group, the interview/discussion will be stopped and you can decide if you would like to continue.

What happens if I tell you something that concerns you about my health or welfare?

In the unlikely event of this happening, we will discuss with you how this should be addressed. If necessary, to protect you, we will report your concern to the appropriate person or bodies.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. If the results of the study are published, your identity will remain confidential.

A lay summary of the results of the study will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

The results of the study will also be used in *Aleema Rahman's PhD* thesis.

Expenses and payments

This study does not have any expenses or require any payments on your behalf other than travel to the place of interview/discussion. Expenses for your travel can be reimbursed.

You will receive a £10 shopping voucher as a thank you for your participation.

Who is funding the research?

The study is being funded by Aston University.

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study.

How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your:

- Name/initials - NHS number - Contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

What are my choices about how my information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can I find out more about how my information is used?

You can find out more about how we use your information

- At www.hra.nhs.uk/information-about-patients/
- Our webpage available at **www.aston.ac.uk/dataprotection**
- By asking one of the research team, or
- By sending an email to **dp_officer@aston.ac.uk**

Who has reviewed the study?

This study was given a favorable ethical opinion by the West Midlands - Edgbaston Research Ethics Committee.

What if I have a concern about my participation in the study?

If you have any concerns about your participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Director of Governance, Mr. John Walter, j.g.walter@aston.ac.uk or telephone 0121 204 4869.

What happens next?

If you would like to take part in this research, please get in touch with the research team to let them know. The researcher will then contact you to tell you more and you will have the chance to ask any further questions.

Research Team

Name	Email address
Aleema Rahman	rahmana9@aston.ac.uk
Dr. Amanda Hall	a.hall@aston.ac.uk
Dr. Helen Pryce	h.pryce-cazalet@aston.ac.uk

Thank you for taking time to read this information sheet. If you have any questions regarding the study, please do not hesitate to ask one of the research team.

Aston University

Site or Collaborator Logo(s)

(to be added)

A qualitative exploration of the impact of long-term glue ear and related hearing loss on children and adolescents with and their information and support needs

Parent/Guardian Information Sheet

Invitation

We would like to invite your child to take part in a research study.

Before you decide if you would like your child to participate, take time to read the following information carefully, and if you wish, discuss it with others, such as your family, friends or colleagues.

Please ask a member of the research team whose contact details can be found at the end of this information sheet if there is anything that is not clear, or if you would like more information before you make your decision.

What is the purpose of the study?

The purpose of this study is to explore the impact that long-term glue ear and related hearing loss has on the social interactions of children and young people.

We aim to observe and describe the social interactions of children and adolescents with long-term glue ear and related hearing loss in a school environment and to understand how they may feel when interacting or anticipating interaction with others. This will help us to understand opinions about how having long-term glue ear and related hearing loss in childhood/adolescence may influence social ability and how this may influence learning at school. We may also see overall how this may affect self-esteem and future aspirations. This will then enable us to identify the relevant support that is needed both within schools and out of school for this group of children/adolescents.

Why has my child been chosen?

Your child is being invited to take part in this study because they meet the criteria for participation in this study, which includes:

- Having glue ear and conductive hearing loss lasting more than 1 year with or without treatment OR
- Having recurrent glue ear and conductive hearing loss over more than 1 year OR
- Being a hearing aid user for glue ear related conductive hearing loss OR
- Having had more than 1 set of grommets or being listed for a second set OR
- Having conductive hearing loss as a result of complications of long-term glue ear or treatment of long-term glue ear

What will happen to my child if they take part?

We would like to observe your child in the school setting to see how they manage with their hearing difficulties. This will include lessons throughout the school day, and after school activities. This is to see how they interact with others both within a learning environment and within a more social context. We will also be talking to your child's teachers to find out more about how their interactive behaviour may potentially be influencing their learning.

How will the observational data be recorded and managed?

If it is OK with you, we will be taking notes during observations. The observations will not be video recorded or audio recorded.

Once the observations are complete, the notes will be typed up fully will be typed into a document by the main researcher. This information that we obtain from the observations might be included in the reporting of the research study, but will be anonymous so nobody will know that it is from your child.

Does my child have to take part?

No. It is up to you and your child to decide whether they take part.

If you do decide that you would like your child to participate, you will be asked to sign and date a consent form and we will obtain assent from your child. Your child would still be free to withdraw from the study at any time without giving a reason.

Will my child taking part in this study be kept confidential?

Yes. A code will be attached to all the data your child provides to maintain confidentiality.

Your child's and your own personal data (name and contact details) will only be used if the researchers need to contact you to arrange study visits or collect data by phone. Analysis of the data your child provided will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

To ensure the quality of the research the study Sponsor may need to access your/your child's data to check that the data has been recorded accurately. If this is required your/your child's personal data will be treated as confidential by the individuals accessing the data.

What are the possible benefits of taking part?

While there are no direct benefits to you or your child of taking part in this study, the data gained will inform us of how long-term glue ear and related hearing loss may affect children in terms of their social interactions as well as how this affects their learning at school. This will all feed in to informing support frameworks for these children.

What are the possible risks and burdens of taking part?

There are no particular risks involved with your child taking part in this study.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. If the results of the study are published, your child's identity will remain confidential.

A lay summary of the results of the study will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

The results of the study will also be used in *Aleema Rahman's PhD* thesis.

What happens if my child tells you something that concerns you about their health or welfare?

In the unlikely event of this happening, we will discuss with you how this should be addressed. If necessary, to protect your child, we will report your concern to the appropriate person or bodies.

Expenses and payments

This study does not have any expenses or require any payments on your behalf.

Your child will receive a £10 shopping voucher as a thank you for taking part in this research.

Who is funding the research?

The study is being funded by Aston University

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study.

How will we use information about your child?

We will need to use information from you/your child and from your child's medical records for this research project.

This information will include your:

- Child's name/initials
- Child's NHS number
- Contact details

People will use this information to do the research or to check your child's records to make sure that the research is being done properly.

People who do not need to know who your child is will not be able to see their name or your contact details. The data will have a code number instead.

We will keep all information about your child safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that your child took part in the study.

What are my choices about how my child's information is used?

- Your child can stop being part of the study at any time, without giving a reason, but we will keep information about your child that we already have.
- We need to manage your child's records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about your child.
- If you agree for your child to take part in this study, you will have the option for them to take part in future research using their data saved from this study.

Where can I find out more about how my child's information is used?

You can find out more about how we use your child's information

- At www.hra.nhs.uk/information-about-patients/
- Our webpage available at **www.aston.ac.uk/dataprotection**
- By asking one of the research team, or
- By sending an email to **dp_officer@aston.ac.uk**

Who has reviewed the study?

This study was given a favorable ethical opinion by the West Midlands - Edgbaston Research Ethics Committee.

What if I have a concern about my child's participation in the study?

If you have any concerns about your child's participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Director of Governance, Mr. John Walter, j.g.walter@aston.ac.uk or telephone 0121 204 4869.

What happens next?

If you would like your child to take part in this research, please get in touch with the research team to let them know. The researcher will then contact you to tell you more and you will have the chance to ask any further questions.

Research Team

Name	Email address
Aleema Rahman	rahmana9@aston.ac.uk
Dr. Amanda Hall	a.hall@aston.ac.uk
Dr. Helen Pryce	h.pryce-cazalet@aston.ac.uk

Thank you for taking time to read this information sheet. If you have any questions regarding the study, please do not hesitate to ask one of the research team.

Aston University

Site or Collaborator Logo(s)

(to be added)

A qualitative exploration of the impact of long-term glue ear and related hearing loss on children and adolescents and their information and support needs

Parent/Guardian Information Sheet

Invitation

We would like to invite your child to take part in a research study.

Before you decide if you want your child would like to participate, take time to read the following information carefully, and if you wish, discuss it with others, such as your family, friends or colleagues.

Please ask a member of the research team whose contact details can be found at the end of this information sheet if there is anything that is not clear, or if you would like more information before you make your decision.

What is the purpose of the study?

This study aims to explore the impact that long-term glue ear and related hearing loss has on the social interactions of children and young people as well as to explore the support needs of families and children with long-term glue ear and related hearing loss.

We aim to observe and describe the social interactions of children and adolescents with long-term glue ear and related hearing loss in a school environment and to understand how they may feel when interacting or anticipating interaction with others. This will help us to understand opinions about how having long-term glue ear and related hearing loss in childhood/adolescence may influence social ability and how this may influence learning at school. We may also see overall how this may affect self-esteem and future aspirations. This will then enable us to identify the relevant support that is needed both within schools and out of school for this group of children/adolescents.

We also wish to explore how these families and children can be better supported by services such as the NHS and educational services from the perspectives of parents, clinicians, teachers and affected young people. Support is limited for these families and children as glue ear is commonly a temporary condition; hence, it is important that the needs of this group are investigated.

Why has my child been chosen?

Your child is being invited to take part in this study because your child meets the criteria for participation in this study, which includes:

- Having glue ear and conductive hearing loss lasting more than 1 year with or without treatment OR
- Having recurrent glue ear and conductive hearing loss over more than 1 year OR
- Being a hearing aid user for glue ear related conductive hearing loss OR
- Having had more than 1 set of grommets or being listed for a second set OR

- Having conductive hearing loss as a result of complications of long-term glue ear or treatment of long-term glue ear

What will happen to my child if they take part?

There are two components of this research that your child can take part in. During the first component we would like to observe your child in the school setting to see how they manage with their hearing difficulties. This will include lessons throughout the school day, and after school activities to see how they interact with others both within a learning environment and within a more social context. We will also be talking to your child's teachers to find out more about how their interactive behaviour may potentially be influencing their learning.

The second part of this research involves your child taking part in a focus group discussion with other young people with long-term glue ear and hearing loss. The discussion will be centered on what support they are currently getting and what support hey feel is needed for families and children with long-term glue ear and hearing loss. The main researcher will be present to facilitate the group and will be taking notes during discussions. Overall, this should take around 60-90 minutes.

How will the information from the observations and conversations that take place during the focus groups be recorded and the information my child provides managed?

If it is OK with you, we will be taking notes during observations. The observations will not be video recorded or audio recorded.

Once the observations are complete, the notes will be typed up fully will be typed into a document by the main researcher. This information that we obtain from the observations might be included in the reporting of the research study but will be anonymous so nobody will know that it is from your child.

If it is OK with you and the parents of the rest of the members of the group, we will audio record the focus group discussion.

The recording will be typed into a document (transcribed) by the main researcher. During the transcription process any names that have been used will be replaced with a pseudonym.

Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy.

Any extracts from the group discussions that are included in the reporting of the study will be anonymous.

Does my child have to take part?

No. It is up to you and your child to decide whether they take part.

Your child can take part in both parts of the research: 1) School observation 2) Focus group or just one if you would prefer that.

If you do decide that you would like your child to participate, you will be asked to sign and date a consent form and we will obtain assent from your child. Your child would still be free to withdraw from the study at any time without giving a reason.

Will my child taking part in this study be kept confidential?

Yes. A code will be attached to all the data your child provides to maintain confidentiality.

Your child's and your own personal data (name and contact details) will only be used if the researchers need to contact you to arrange study visits or collect data by phone. Analysis of the data your child provided will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

To ensure the quality of the research the study Sponsor may need to access your/your child's data to check that the data has been recorded accurately. If this is required your/your child's personal data will be treated as confidential by the individuals accessing the data.

If you agree to your child taking part in a focus group, full confidentiality cannot be guaranteed on behalf of the other focus group participants, although all participants will be asked to maintain confidentiality at the start of the focus group.

What are the possible benefits of taking part?

While there are no direct benefits to you or your child of taking part in this study, the data gained will inform us of how long-term glue ear and related hearing loss may affect children in terms of their social interactions as well as how this affects their learning at school. This will all feed in to informing support frameworks for these children. You will be helping to potentially improve services for children and families like yours.

What are the possible risks and burdens of taking part?

While the risks of this study are minimal, the risk of potential distress to your child may be present when discussing support needs if any sensitive information is discussed. Although this risk is minimal, if your child does become distressed, the discussion will be stopped and they will only need to continue to participate if they wish.

What happens if my child tells you something that concerns you about their health or welfare?

In the unlikely event of this happening, we will discuss with you how this should be addressed. If necessary, to protect your child, we will report your concern to the appropriate person or bodies.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. If the results of the study are published, your child's identity will remain confidential.

A lay summary of the results of the study will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

The results of the study will also be used in *Aleema Rahman's* PhD thesis.

Expenses and payments

Focus groups will take part at Aston University and you will need to accompany your child. Travel to Aston University will need to be arranged. Expenses for your travel can be reimbursed.

Refreshments will be provided during focus group discussions.

Your child will receive a £10 shopping voucher as a thank you for their participation.

Who is funding the research?

The study is being funded by Aston University

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study.

How will we use information about you?

We will need to use information from you/your child and from your child's medical records for this research project.

This information will include:

- Child's name/initials
- Child's NHS number
- Contact details

People will use this information to do the research or to check your child's records to make sure that the research is being done properly.

People who do not need to know who you or your child are will not be able to see your name/your child's name or contact details. Your data will have a code number instead.

We will keep all information about you and your child safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that your child took part in the study.

What are my choices about how my child's information is used?

- Your child can stop being part of the study at any time, without giving a reason, but we will keep information about your child that we already have.
- We need to manage your child's records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about your child.
- If you agree for your child to take part in this study, you will have the option for them to take part in future research using their data saved from this study.

Where can I find out more about how my child's information is used?

You can find out more about how we use your child's information

- At www.hra.nhs.uk/information-about-patients/
- Our webpage available at **www.aston.ac.uk/dataprotection**
- By asking one of the research team, or

- By sending an email to **dp_officer@aston.ac.uk**

Who has reviewed the study?

This study was given a favorable ethical opinion by the West Midlands - Edgbaston Research Ethics Committee.

What if I have a concern about my child's participation in the study?

If you have any concerns about your child's participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Director of Governance, Mr. John Walter, j.g.walter@aston.ac.uk or telephone 0121 204 4869.

What happens next?

If you would like your child to take part in this research, please get in touch with the research team to let them know. The researcher will then contact you to tell you more and you will have the chance to ask any further questions.

Research Team

Name	Email address
Aleema Rahman	rahmana9@aston.ac.uk
Dr Amanda Hall	a.hall@aston.ac.uk
Dr Helen Pryce	h.pryce-cazalet@aston.ac.uk

Thank you for taking time to read this information sheet. If you have any questions regarding the study please don't hesitate to ask one of the research team.

Aston University

Site or Collaborator Logo(s)

(to be added)

A qualitative exploration of the impact of long-term glue ear and related hearing loss on children and adolescents and their information and support needs

Participant Information Sheet (Teachers)

Invitation

We would like to invite you to take part in a research study.

Before you decide if you would like to participate, take time to read the following information carefully, and if you wish, discuss it with others, such as your family, friends or colleagues.

Please ask a member of the research team whose contact details can be found at the end of this information sheet if there is anything that is not clear, or if you would like more information before you make your decision.

What is the purpose of the study?

The aim of this study is to explore the impact that long-term glue ear and related hearing loss has on the social interactions of children and adolescents. We aim to observe and describe the social interactions of children and adolescents with long-term glue ear and related hearing loss in a school environment and to understand how they may feel when interacting or anticipating interaction with others. As well as observing children/adolescents at school, we would like to find out more from their teachers. This will help us to understand any effect that having long-term glue ear and related hearing loss in childhood/adolescence has on social ability and how this may influence learning at school. This then will enable us to identify the support that is needed both within schools and out of school for this group of children/adolescents.

Why have I been chosen?

You are being invited to take part in this study because you are a teacher of one of the students who has agreed to take part in this study. As their teacher, we would like to obtain more information on their social interactive behaviour in class as well as your views on the support needs of families and children with long-term glue ear and related hearing loss.

What will happen to me if I take part?

Taking part in this study will involve you being interviewed on your views on how the child's interactive behaviour may influence their learning. You will also be asked questions to obtain your views on the general support needs children with long-term glue ear and related hearing loss and their families. Interviews will take place after the child has been observed and will last around 15-30 minutes.

How will the conversation that takes place during the interview be recorded and the information I provide managed?

If it is OK with you, when we talk to you, we will audio record the conversation.

The recording will be typed into a document (transcribed) by the main researcher. During the transcription process any names that have been used will be replaced with a pseudonym.

Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy.

Any extracts from the interview that are included in the reporting of the study will be anonymous.

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part.

If you do decide to participate, you will be asked to sign and date a consent form. You would still be free to withdraw from the study at any time without giving a reason.

Will my taking part in this study be kept confidential?

Yes. A code will be attached to all the data you provide to maintain confidentiality.

Your personal data (name and contact details) will only be used if the researchers need to contact you to arrange study visits or collect data by phone. Analysis of your data will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

To ensure the quality of the research the study Sponsor may need to access your data to check that the data has been recorded accurately. If this is required your personal data will be treated as confidential by the individuals accessing your data.

What are the possible benefits of taking part?

While there are no direct benefits to you of taking part in this study, the data gained will inform us of how long-term glue ear and related hearing loss may affect children and adolescents in terms of their social interactions and emotional well-being as well as how this affects their learning at school and career aspirations. This will all feed in to informing support frameworks for these children and adolescents.

What are the possible risks and burdens of taking part?

The risks of this study are minimal; however, some topics of discussion may be upsetting. Although this risk is unlikely, if you do become distressed, the interview will be stopped and you will only need to continue to participate if you wish.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. If the results of the study are published, your identity will remain confidential.

A lay summary of the results of the study will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

The results of the study will also be used in *Aleema Rahman's* PhD thesis.

Expenses and payments

There are no expenses or payments required on your behalf.

Who is funding the research?

The study is being funded by Aston University

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study.

How will we use information about you?

We will need to use information from you for this research project. This information will include your:

- Name/initials
- Contact details

People will use this information to do the research or to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

What are my choices about how my information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can I find out more about how my information is used?

You can find out more about how we use your information

- Our webpage available at **www.aston.ac.uk/dataprotection**
- By asking one of the research team, or
- By sending an email to **dp_officer@aston.ac.uk**

Who has reviewed the study?

This study was given a favorable ethical opinion by the West Midlands - Edgbaston Research Ethics Committee.

What if I have a concern about my participation in the study?

If you have any concerns about participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Director of Governance, Mr. John Walter, j.g.walter@aston.ac.uk or telephone 0121 204 4869.

What happens next?

If you would like to take part in this research, please get in touch with the research team to let them know. The researcher will then contact you to tell you more and you will have the chance to ask any further questions.

Research Team

Name	Email address
Aleema Rahman	rahmana9@aston.ac.uk
Dr. Amanda Hall	a.hall@aston.ac.uk
Dr. Helen Pryce	h.pryce-cazalet@aston.ac.uk

Thank you for taking time to read this information sheet. If you have any questions regarding the study please don't hesitate to ask one of the research team.

Aston University

Site or Collaborator Logo(s)

(to be added)

A qualitative exploration of the impact of long-term glue ear and related hearing loss on children and adolescents and their information and support needs

Participant Information Sheet

Invitation

We would like to invite you to take part in a research study.

Before you decide if you would like to participate, take time to read the following information carefully, and if you wish, discuss it with others, such as your family, friends or colleagues.

Please ask a member of the research team whose contact details can be found at the end of this information sheet if there is anything that is not clear, or if you would like more information before you make your decision.

What is the purpose of the study?

The aim of this study is to explore the information and support needs of families and children with long-term glue ear and related hearing loss in managing living with the condition. This involves exploring how these families and children can be better supported by services such as the NHS and educational services from the perspectives of parents, clinicians, teachers and affected young people. Support is limited for these families and children as glue ear is commonly a temporary condition; hence, it is important that the needs of this group are investigated.

Why have I been chosen?

You are being invited to take part in this study because you meet the criteria for participation in this study, which includes having a child, who:

- Has glue ear and conductive hearing loss lasting more than 1 year with or without treatment OR
- Has recurrent glue ear and conductive hearing loss over more than 1 year OR
- Is a hearing aid user for glue ear related conductive hearing loss OR
- Has had more than 1 set of grommets or is being listed for a second set OR
- Has conductive hearing loss as a result of complications of long-term glue ear or treatment of long-term glue ear

What will happen to me if I take part?

You will take part in a focus group discussion with other parents of children/young people with long-term glue ear and related hearing loss. Using a visual mapping technique, you will be involved in a

discussion about what support is required for families and children with long-term glue ear and related hearing loss. Each of you who make up the focus group will create your own map demonstrating where you feel support is needed for children and their families and from whom and then discuss this with the group. The main researcher will be present to facilitate the group and will be taking notes during discussions. Overall, this should take around 60-90 minutes.

How will the conversations that take place during the focus groups be recorded and the information I provide managed?

If it is OK with you and the rest of the group members, we will audio record the focus group discussion.

The recording will be typed into a document (transcribed) by the main researcher. During the transcription process any names that have been used will be replaced with a pseudonym.

Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy.

Any extracts from the group discussions that are included in the reporting of the study will be anonymous.

Do I have to take part?

No. It is up to you to decide whether you wish to take part.

If you do decide to participate, you will be asked to sign and date a consent form. You would still be free to withdraw from the study at any time without giving a reason.

Will my taking part in this study be kept confidential?

Yes. A code will be attached to all the data you provide to maintain confidentiality.

Your personal data (name and contact details) will only be used if the researchers need to contact you to arrange study visits or collect data by phone. Analysis of your data will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

To ensure the quality of the research the study Sponsor may need to access your data to check that the data has been recorded accurately. If this is required your personal data will be treated as confidential by the individuals accessing your data.

If you agree to take part in a focus group full confidentiality cannot be guaranteed on behalf of the other focus group participants, although all participants will be asked to maintain confidentiality at the start of the focus group.

What are the possible benefits of taking part?

While there are no direct benefits to you of taking part in this study, the data gained will feed in to informing support frameworks for families and children with long-term glue ear and related hearing loss. You will be helping to improve services for children and families like yours.

What are the possible risks and burdens of taking part?

While the risks of this study are minimal, there is the risk of you potentially becoming distressed when discussing support needs if any sensitive information is discussed. Although this risk is minimal, if you do become distressed, the discussion will be stopped and you will only need to continue to participate if you wish.

What happens if I tell you something that concerns you about the health or welfare of myself and my child?

In the unlikely event of this happening, we will discuss with you how this should be addressed. If necessary, to protect you and your child, we will report your concern to the appropriate person or bodies.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. If the results of the study are published, your identity will remain confidential.

A lay summary of the results of the study will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

The results of the study will also be used in *Aleema Rahman's* PhD thesis.

Expenses and payments

Travel to the venue where the focus group will take place – Aston University, will need to be arranged. Expenses for your travel can be reimbursed.

Refreshments will be provided during focus group discussions.

You will receive a £10 shopping voucher as a thank you for taking part in this study.

Who is funding the research?

The study is being funded by Aston University

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study.

How will we use information about you?

We will need to use information from you for this research project. This information will include your:

- Name/initials
- Contact details

People will use this information to do the research or to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are my choices about how my information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can I find out more about how my information is used?

You can find out more about how we use your information

- At www.hra.nhs.uk/information-about-patients/
- Our webpage available at **www.aston.ac.uk/dataprotection**
- By asking one of the research team, or
- By sending an email to **dp_officer@aston.ac.uk**

Who has reviewed the study?

This study was given a favorable ethical opinion by the West Midlands - Edgbaston Research Ethics Committee.

What if I have a concern about my participation in the study?

If you have any concerns about participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Director of Governance, Mr. John Walter, j.g.walter@aston.ac.uk or telephone 0121 204 4869.

What happens next?

If you would like to take part in this research, please get in touch with the research team to let them know. The researcher will then contact you to tell you more and you will have the chance to ask any further questions.

Research Team

Name	Email address
Aleema Rahman	rahmana9@aston.ac.uk
Dr Amanda Hall	a.hall@aston.ac.uk
Dr Helen Pryce	h.pryce-cazalet@aston.ac.uk

Thank you for taking time to read this information sheet. If you have any questions regarding the study please don't hesitate to ask one of the research team.

Aston University

Site or Collaborator Logo(s)

(to be added)

A qualitative exploration of the impact of long-term glue ear and related hearing loss on children and adolescents and their information and support needs

Participant Information Sheet (Clinicians)

Invitation

We would like to invite you to take part in a research study.

Before you decide if you would like to participate, take time to read the following information carefully, and if you wish, discuss it with others, such as your family, friends or colleagues.

Please ask a member of the research team whose contact details can be found at the end of this information sheet if there is anything that is not clear, or if you would like more information before you make your decision.

What is the purpose of the study?

The aim of this study is to explore the information and support needs of families and children with long-term glue ear and hearing loss in managing living with the condition. This involves exploring how these families and children can be better supported by services such as the NHS and educational services from the perspectives of parents, clinicians, teachers and affected young people. Support is limited for these families and children as glue ear is commonly a temporary condition; hence, it is important that the needs of this group are investigated.

Why have I been chosen?

You are being invited to take part in this study because you are part of the clinical team who assesses/treats/provides care to children and adolescents who:

- Have or have had glue ear and hearing loss lasting more than 1 year with or without treatment past the age of 7 years
- Have or have had a history of recurrent glue ear and conductive hearing loss over more than 1 year past the age of 7 years
- Wear or have worn a hearing aid for glue ear related conductive hearing loss past the age of 7 years
- Are 7 years and above and have had more than 1 set of grommets or are listed for a second set
- Have conductive hearing loss as a result of complications of long-term glue ear or treatment of long-term glue ear

It is important that we get your views on the support needs of families and children with long-term glue ear and hearing loss as you are regularly involved with these individuals.

What will happen to me if I take part?

You will be interviewed on your own or in a focus group with your colleagues at your workplace, on your views surrounding the support needs of families and children with long-term glue ear and related hearing loss. This should take around 30-60 minutes.

How will the conversations that take place during the interview/focus group be recorded and the information I provide managed?

If it is OK with you (and the other group members if taking part in a focus group), when we talk to you, we will audio record the conversation.

The recording will be typed into a document (transcribed) by the main researcher. During the transcription process any names that have been used will be replaced with a pseudonym.

Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy.

Any extracts from the interview that are included in the reporting of the study will be anonymous.

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part.

If you do decide to participate, you will be asked to sign and date a consent form. You would still be free to withdraw from the study at any time without giving a reason.

Will my taking part in this study be kept confidential?

Yes. A code will be attached to all the data you provide to maintain confidentiality.

Your personal data (name and contact details) will only be used if the researchers need to contact you to arrange study visits or collect data by phone. Analysis of your data will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

To ensure the quality of the research the study Sponsor may need to access your data to check that the data has been recorded accurately. If this is required your personal data will be treated as confidential by the individuals accessing your data.

What are the possible benefits of taking part?

While there are no direct benefits to you of taking part in this study, the data gained will feed in to informing support frameworks for families and children with long-term OME and hearing loss.

What are the possible risks and burdens of taking part?

While the risks of this study are minimal, some topics of discussion may be upsetting. Although this risk is minimal, if you do become distressed, the interview will be stopped and you will only need to continue to participate if you wish.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. If the results of the study are published, your identity will remain confidential.

A lay summary of the results of the study will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

The results of the study will also be used in *Aleema Rahman's* PhD thesis.

Expenses and payments

There are no expenses or payments required on your behalf.

Who is funding the research?

The study is being funded by Aston University

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study.

How will we use information about you?

We will need to use information from you for this research project. This information will include your:

- Name/initials
- Contact details

People will use this information to do the research or to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

What are my choices about how my information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can I find out more about how my information is used?

You can find out more about how we use your information

- At www.hra.nhs.uk/information-about-patients/
- Our webpage available at **www.aston.ac.uk/dataprotection**
- By asking one of the research team, or
- By sending an email to **dp_officer@aston.ac.uk**

Who has reviewed the study?

This study was given a favorable ethical opinion by the West Midlands - Edgbaston Research Ethics Committee.

What if I have a concern about my participation in the study?

If you have any concerns about participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Director of Governance, Mr. John Walter, j.g.walter@aston.ac.uk or telephone 0121 204 4869.

What happens next?

If you would like to take part in this research, please get in touch with the research team to let them know. The researcher will then contact you to tell you more and you will have the chance to ask any further questions.

Research Team

Name	Email address
Aleema Rahman	rahmana9@aston.ac.uk
Dr. Amanda Hall	a.hall@aston.ac.uk
Dr. Helen Pryce	h.pryce-cazalet@aston.ac.uk

Thank you for taking time to read this information sheet. If you have any questions regarding the study please don't hesitate to ask one of the research team.

Appendix VI

Poster adverts

IRAS ID: 263417, Version 0.2, 09 January 2020

Is your child aged 7 or above?

Do they have long-term glue ear and related hearing loss?

Long-term glue ear refers to ongoing or recurrent glue ear or related problems past the age of 7 years which may have resulted in hearing loss

If so, you may be able to help us!

We would like to invite you and your child to take part in our research which involves finding out what it is like to live with long-term glue ear and related hearing loss.

Email us to find out more!

Receive a £10 shopping voucher for taking part!

If you would like to be involved and for further information please contact Aleema Rahman:

rahmana9@aston.ac.uk

Aston University

IRAS ID: 263417, Version 0.1, 13 June 2019

Appendix VII

Email/letter to school Head Teachers

Dear Sir/Madam,

I am a PhD student from Aston University investigating the impact of long-term glue ear and related hearing loss in children. My research involves observing children with hearing loss at school - during their lessons and during any after school activities or clubs that they are involved with, to understand the impact of their hearing loss on their education and social interactions.

Your student (name and year) would like to take part in my research study and has agreed that I can contact you to ask for your permission. If you agree, I would like to observe [student's name] in school over a period of 3 days at a time that is convenient. During my research, I will solely be making observations of [student's name] behaviour and interactions, and not of any other children. I would also like to interview [student's name] teacher if they consent.

I understand that while I have received consent from the child and their parents, this arrangement also requires your involvement as I am required to be on your school grounds in order to conduct my research. The study has received ethical approval from the NHS Health Research Authority Research and the Research Ethics Committee. The study is sponsored by Aston University and covered by the University insurance. I have a DBS certificate, and am also a qualified audiologist, registered with the RCCP.

If you are happy for this observation to be carried out on your school grounds, please let me know so we can arrange an appropriate time period for the observation to be carried out.

If you would like any further information, please let me know and I will be happy to discuss this further.

Yours faithfully,

Aleema Rahman,

PhD student

And

Dr Amanda Hall

Lecturer in Audiology and PhD Supervisor

Audiology, School of Life & Health Sciences

Aston University

Appendix VIII

Screening questions

Screening questions for parents of 7-16 year olds (Study 1)

How old is your child?

Do they have long-term glue ear and related hearing loss? Conductive hearing loss?

How long have they had glue ear and hearing loss?

Do they/ have they had any complications from glue ear or treatment? Cause of hearing loss? Permanent?

Have they had any ear surgery?

Do they have sensorineural hearing loss?

Do they use a hearing aid? Conventional? Bone conduction?

Have they had grommets? How many sets?

Do they attend school? What year? Which school? Birmingham?

Do they speak English?

Do they have any learning difficulties or special educational needs? Do they get any support for this?

Screening questions for 16-18 year olds (Study 1)

How old are you?

Do you have long-term glue ear and related hearing loss? Conductive hearing loss?

How long have you had glue ear and related hearing loss?

Do you have/have you had any complications from glue ear or treatment? Cause of hearing loss? Permanent?

Have you had any ear surgery?

Do you have sensorineural hearing loss?

Do you use a hearing aid? Conventional? Bone conduction?

Have you had grommets? How many sets?

Do you go to school? Sixth form? College? What year? Birmingham?

Speak English?

Do you have any learning difficulties or special educational needs? Do you get any support for this?

Screening questions for parents (Study 2)

How old is your child?

Do they have long-term glue ear and related hearing loss? Conductive hearing loss?

How long have they had glue ear and hearing loss?

Do they/ have they had any complications from glue ear or treatment? Cause of hearing loss? Permanent?

Have they had any ear surgery?

Do they have sensorineural hearing loss?

Do they use a hearing aid? Conventional? Bone conduction?

Have they had grommets? How many sets?

Do you speak fluent English? Enough to take part in a focus group?

Do you live in Birmingham?

Screening questions for 16-24 year olds (Study 2)

How old are you?

Do you have/have you had long-term glue ear and related hearing loss? Conductive hearing loss?

How long have you had glue ear and related hearing loss?

Do you have/have you had any complications from glue ear or treatment? Cause of hearing loss? Permanent?

Have you had any ear surgery?

Do you have sensorineural hearing loss?

Do you use a hearing aid? Conventional? Bone conduction?

Have you had grommets? How many sets?

Speak English? Enough to take part in a focus group?

Do you live in Birmingham?

Screening questions for clinicians (Study 2)

Are you an ENT consultant or an Audiologist?

Do you work with paediatric patients?

Do you work within the West Midlands?

Appendix IX

Consent forms

Aston University

Site or Collaborator Logo(s)
(to be added)

A qualitative exploration of the impact of long-term glue ear and related hearing loss on children and adolescents and their information and support needs

Consent Form

Name of researcher: Aleema Rahman

Name of Chief Investigator: Dr Amanda Hall

Please initial boxes

1.	I confirm that I have read and understand the Participant Information Sheet (Version 0.4, December 2019) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.		
2.	I understand that my child's participation is voluntary and that they are free to withdraw at any time, without giving any reason and without their legal rights being affected.		
3.	I agree to my child's personal data and data relating to them collected during the study being processed as described in the Participant Information Sheet.		
4.	I understand that if during the study my child tells the research team something that causes them to have concerns in relation to my child's health and/or welfare they may need to breach my child's confidentiality.		
5.	I agree to my child's anonymised data being used by research teams for future research.		
6.	I agree to my child's personal data, being processed for the purposes of inviting them to participate in future research projects. I understand that we may opt out of receiving these invitations at any time.	Yes	No
7.	I agree to my child taking part in this study.		

Name of parent	Date	Signature

Name of participant

Name of Person receiving consent.	Date	Signature

Child's assent obtained ☐ Yes ☐ No

Name of participant		Date

Name of Person receiving consent.	Date	Signature

Aston University

Site or Collaborator Logo(s)

(to be added)

A qualitative exploration of the impact of long-term glue ear and related hearing loss on children and adolescents and their information and support needs

Consent Form

Name of researcher: Aleema Rahman

Name of Chief Investigator: Dr Amanda Hall

Please initial boxes

1.	I confirm that I have read and understand the Participant Information Sheet (Version 0.5, January 2020) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.		
2.	I understand that my child's participation is voluntary and that they are free to withdraw at any time, without giving any reason and without my child's legal rights being affected.		
3.	I agree to my child's personal data and data relating to my child collected during the study being processed as described in the Participant Information Sheet.		
4.	I understand that if during the study my child tells the research team something that causes them to have concerns in relation to my child's health and/or welfare they may need to breach my child's confidentiality.		
5.	I agree to the focus group/interview being audio recorded and to anonymised direct quotes from my child being used in publications resulting from the study.		
6.	I agree to my child's anonymised data being used by research teams for future research.		
7.	I agree to my child's personal data, being processed for the purposes of inviting me to participate in future research projects. I understand that I may opt out of receiving these invitations at any time.	Yes	No
8.	I agree to my child taking part in this study.		

Name of parent	Date	Signature

Name of participant

Name of Person receiving consent.	Date	Signature

Child's assent obtained ☐ Yes ☐ No

Name of participant	Date

Name of Person receiving consent.	Date	Signature

Aston University

Site or Collaborator Logo(s)
(to be added)

A qualitative exploration of the impact of long-term glue ear and related hearing loss on children and adolescents and their information and support needs

Consent Form

Name of researcher: Aleema Rahman

Name of Chief Investigator: Dr Amanda Hall

Please initial boxes

1.	I confirm that I have read and understand the Participant Information Sheet (Version 0.5, January 2020) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.		
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected.		
3.	I agree to my personal data and data relating to me collected during the study being processed as described in the Participant Information Sheet.		
4.	I understand that if during the study I tell the research team something that causes them to have concerns in relation to my health and/or welfare they may need to breach my confidentiality.		
5.	I agree to the focus group/interview being audio recorded and to anonymised direct quotes from me being used in publications resulting from the study.		
6.	I agree to my anonymised data being used by research teams for future research.		
7.	I agree to my personal data, being processed for the purposes of inviting me to participate in future research projects. I understand that I may opt out of receiving these invitations at any time.	Yes	No
8.	I agree to take part in this study.		

Name of participant	Date	Signature
Name of Person receiving consent.	Date	Signature

Aston University

Site or Collaborator Logo(s)
(to be added)

A qualitative exploration of the impact of long-term glue ear and related hearing loss on children and adolescents with and their information and support needs

Consent Form

Name of researcher: Aleema Rahman

Name of Chief Investigator: Dr Amanda Hall

Please initial boxes

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3.	I agree to my personal data and data relating to me collected during the study being processed as described in the Participant Information Sheet.		
4.	I understand that if during the study I tell the research team something that causes them to have concerns in relation to my health and/or welfare they may need to breach my confidentiality.		
5.	I agree to my interview being audio recorded and to anonymised direct quotes from me being used in publications resulting from the study.		
6.	I agree to the focus group/interview being audio recorded and to anonymised direct quotes from me being used in publications resulting from the study.		
7.	I agree to my anonymised data being used by research teams for future research.		
8.	I agree to my personal data, being processed for the purposes of inviting me to participate in future research projects. I understand that I may opt out of receiving these invitations at any time.	Yes	No
9.	I agree to take part in this study.		

Name of participant	Date	Signature
Name of Person receiving consent.	Date	Signature

Aston University

Site or Collaborator Logo(s)
(to be added)

A qualitative exploration of the impact of long-term glue ear and related hearing loss on children and adolescents and their information and support needs

Consent Form

Name of researcher: Aleema Rahman

Name of Chief Investigator: Dr Amanda Hall

Please initial boxes

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5.	I agree to the interview being audio recorded and to anonymised direct quotes from me being used in publications resulting from the study.		
6.	I agree to my anonymised data being used by research teams for future research.		
7.	I agree to my personal data, being processed for the purposes of inviting me to participate in future research projects. I understand that I may opt out of receiving these invitations at any time.	Yes	No
8.	I agree to take part in this study.		

Name of participant _____ Date _____ Signature _____

_____	_____	_____
Name of Person receiving consent.	Date	Signature

Aston University

Site or Collaborator Logo(s)
(to be added)

A qualitative exploration of the impact of long-term glue ear and related hearing loss on children and adolescents and their information and support needs

Consent Form

Name of researcher: Aleema Rahman

Name of Chief Investigator: Dr Amanda Hall

Please initial boxes

1.	I confirm that I have read and understand the Participant Information Sheet (Version 0.5, January 2020) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.		
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected.		
3.	I agree to my personal data and data relating to me collected during the study being processed as described in the Participant Information Sheet.		
4.	I understand that if during the study I tell the research team something that causes them to have concerns in relation to my health and/or welfare they may need to breach my confidentiality.		
5.	I agree to the focus group/interview being audio recorded and to anonymised direct quotes from me being used in publications resulting from the study.		
6.	I agree to my anonymised data being used by research teams for future research.		
7.	I agree to my personal data, being processed for the purposes of inviting me to participate in future research projects. I understand that I may opt out of receiving these invitations at any time.	Yes	No
8.	I agree to take part in this study.		

Name of participant	Date	Signature
Name of Person receiving consent.	Date	Signature

Aston University

Site or Collaborator Logo(s)
(to be added)

A qualitative exploration of the impact of long-term glue ear and related hearing loss on children and adolescents and their information and support needs

Consent Form

Name of researcher: Aleema Rahman

Name of Chief Investigator: Dr Amanda Hall

Please initial boxes

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2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected.		
3.	I agree to my personal data and data relating to me collected during the study being processed as described in the Participant Information Sheet.		
4.	I understand that if during the study I tell the research team something that causes them to have concerns in relation to my health and/or welfare they may need to breach my confidentiality.		
5.	I agree to the focus group/interview being audio recorded and to anonymised direct quotes from me being used in publications resulting from the study.		
6.	I agree to my anonymised data being used by research teams for future research.		
7.	I agree to my personal data, being processed for the purposes of inviting me to participate in future research projects. I understand that I may opt out of receiving these invitations at any time.	Yes	No
8.	I agree to take part in this study.		

Name of participant	Date	Signature
Name of Person receiving consent.	Date	Signature

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