

Acknowledgements

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Abstract

Introduction

Methods for measuring frailty over-emphasise physical health, and consensus for a more holistic approach is increasing. However, holistic tools have had mixed success in meeting the validation criteria required of a frailty index. We report on the further development and validation of a Frailty Tool designed for use in the community with a greater emphasis on psychological markers, Holland *et al*'s Community-Oriented Frailty Index (COM-FI).

Method

A total of 351 participants aged 58-96 were recruited from Retirement Villages and local communities across the West Midlands of the UK. Participants completed a series of measures designed to assess frailty and outcomes associated with frailty over a 2-year period.

Results

All three candidate items ('polypharmacy', 'exercise frequency', and the Coronary Heart Disease and Diabetes 'joint effect') were incorporated into the tool, and one variable, 'falls' was removed from the index. The revised COM-FI was shown to be valid and met Rockwood's validation criteria (Rockwood *et al.*, 2005), with the exception that in this specific sample there was no significant gender difference and the index did not predict mortality.

Discussion

Overall, the COM-FI is a valid and reliable tool, although the capacity for the COM-FI to predict mortality over a 2-year period remains inconclusive given the small numbers of people at the higher ends of the frailty range. Prediction of need for social care was good, showing the utility of this community based tool.

Frailty is a multidimensional, pre-disability syndrome, defined as a heightened state of vulnerability to adverse outcomes when exposed to a stressor, such as having a fall (Clegg Young, Iliffe, Rikkert, & Rockwood, 2013), that can result in a significant reduction to quality of life (Kojima, Iliffe, Jivraj, & Walters, 2016). The transition from robust to frail is a process of deterioration that occurs over an extended period of time predisposes individuals to disability, loss of independence, and increases the risk of hospitalisation, health care use, dementia, poor quality of life, and mortality (Rockwood, Mitnitski, Song, Steen, & Skoog, 2006).

A consensus on how best to operationalise and assess frailty remains elusive (Rodriguez-Manas *et al.*, 2012). Two definitions are generally accepted within clinical settings. One defines frailty as a single physical phenotype (Fried *et al.*, 2001) and the other defines frailty as an accumulation of impairments and illnesses (Rockwood, & Mitnitski, 2007). Each was used to build well-recognised frailty indices: the Frailty Phenotype (Fried *et al.*, 2001), and the Canadian Study of Health and Aging frailty index respectively (CHSA; Rockwood, 2005). However, both draw criticism for their focus on physical frailty markers to determine frailty severity, and calls for a holistic approach to frailty assessment have increased (Escourrou *et al.*, 2017). Unfortunately, indices that have attempted to build a multidimensional tool, such as the Tilburg Frailty Indicator (Gobbens *et al.*, 2010), and the Groningen Frailty Index (Peters, Boter, Buskens, & Slaets, 2012), have failed to meet Rockwood's validation criteria (Dent, Kowal, & Hoogendijk, 2016). That is, there should be a significant gender difference in relation to frailty severity, frailty should be positively associated with chronological age, and the model should predict hospitalisation and death. We postulate that to build a holistic index, an existing, validated, frailty index should be amended to incorporate non-physical markers into assessment, providing this does not compromise reliability and validity of the tool.

Our frailty index, the Community-Oriented Frailty Index (COM-FI), originally developed by Holland *et al.* (2015), utilises the accumulation of deficits foundation of frailty, meaning it is flexible to the inclusion of new markers (on the condition variables are significantly associated with frailty, Rockwood, & Mitnitski, 2007), and is comprised of variables used in the Frailty Phenotype (Fried *et al.*, 2001), the CSHA index (Rockwood, 2005) and the frailty index derived from the English Longitudinal Study of Ageing (Nazroo, & Marshall, 2013), and contains a large psychological component in the assessment criteria (17 of the 50 variables assess psychological markers). An important prognostic strength of the tool is its

ability to predict amount of formal care an individual requires based on their frailty severity. This makes it specifically useful in integrated care settings.

However, the COM-FI requires further development as the field develops, specifically by testing whether adding assessments of physical activity (which is strongly associated with higher frailty severity; Brinkman *et al.*, 2018) and polypharmacy (taking four or more prescribed medications) into the model is valid. The use of either or both markers in multiple frailty indices (Fried *et al.*, 2001; Gobbens *et al.*, 2010; Martins *et al.*, 2019; Peters *et al.*, 2012; Rockwood, & Mitnitski, 2007) warrants them an *a priori* status. The original inclusion of ‘falls’ as a predictor variable is also queried, with falls considered an outcome and not a predictor (Ensrud *et al.*, 2007).

Finally, the use of an accumulation of deficits approach to frailty assessment misrepresents the importance of severe health markers. For instance, a diagnosis of dementia is given the same weight as a diagnosis of high blood pressure (as both would receive a score of 1) despite dementia arguably being the more severe condition. Unfortunately, weighting severe markers to address this imbalance inhibits generalisability and usability of the model (Rockwood, & Mitnitski, 2007). Therefore we suggest incorporating ‘joint effects’ into the model.

A joint effect is where the combined effect of specific illnesses results in a significantly worse health outcome than anticipated based on the individual effect of each illness (Köhler *et al.*, 2012). Based on the markers used in the COM-FI, and currently identified joint effects, we considered inclusion of a Coronary Heart Disease and Diabetes joint effect, which has shown to be associated with impaired cognition (Verhagen, Borchelt, & Smith, 2003) and increase risk of deterioration towards death (Mayer Jr *et al.*, 2018).

These adjustments, if confirmed, would warrant re-validation of the COM-FI. Therefore, the aims of this paper are as follows:

1. Assess suitability of candidate items for inclusion into the Frailty Index based on Rockwood and Mitnitski’s (2007) variable inclusion requirement (i.e. a significant relationship must be present between the variable and frailty).
2. Assess validity and reliability of the COM-FI using standard analytical procedures, against Rockwood’s (2005) validation criteria, Holland’s (2015) predictions of formal care, and Clegg *et al* (2013) and Kojima *et al*’s (2016) conclusions about the impact of frailty on the risk of a fall and quality of life respectively.

Method

Participants

Data was collected as part of a larger study (Holland *et al.*, 2015; 2018; 2019). Participants were recruited from retirement villages and local communities. Participants from the retirement villages were recruited according to how long they had lived there: baseline (recently moved in), 3, 12, 15-18, or 24 months. Assessments were repeated along the trajectory outlined up to the 2-year period. For example, if a participant's first assessment was at 12-months, they would only complete two more assessments up to the 2-year point. Of the 351 participants who took part in the project, 122 completed a single assessment, 68 completed two, 36 completed three, 114 completed four, and 11 completed five assessments.

Participants recruited from local communities were allocated to a data collection point to match the age of residents for each time point. There were 89 participants from local communities across the West Midlands of the UK (32 male, 57 female, aged 59-88) and 262 participants from 18 retirement villages (104 male, 158 female, aged 57-96), a total of 351.

Leniency was given towards the inclusion of participants under the age of 65 for two reasons. Firstly, residents living ExtraCare retirement villages have higher frailty scores on average than individuals living in local communities (Holland *et al.*, 2015; 2017; 2019), therefore participants below the age of 65 were considered suitable for the study. Secondly, frailty is shown to develop earlier in individuals living in areas of high deprivation and health inequalities (Hanlon *et al.*, 2018), and as the current index was developed for community use, a broader participant age range is more applicable as part of the validation procedure for the COM-FI.

Procedure

Participants completed a series of measures and questionnaires designed to assess frailty, and frailty outcomes (formal care hours received on a weekly basis, number of falls and hospital visits over the past 12-months, and quality of life). This process was repeated at each data collection point.

Ethics

Informed consent was gained by providing participants with an information sheet outlining their rights of withdrawal and anonymity, what the study entailed, and the duty of care researchers have towards them. Participants were offered the opportunity to ask questions for verification purposes. Prior to inclusion, participants were judged to have the capacity to give informed consent under the Mental Capacity Act of 2007 and the 2 Stage Test of Capacity (Mental Capacity Act, 2008). As participants were fully briefed prior to the participation, no debriefing was required. Identifying participant information was kept on a password protected computer separate to the data files, the document itself was also password protected, and raw data was kept in a locked cabinet. All ethical procedures are aligned with BPS requirements.

Measures

Frailty and outcomes were assessed using a series of measures: a general health assessment examining participant declared diagnoses and self-rated health, grip strength, walking speed, sit-to-stand speed, and feelings of exhaustion; activities and instrumental activities of daily living (Lawton, & Brody, 1969); hospital anxiety and depression scale (HADS; Zigmond, & Snaith, 1983); functional limitations profile (FLP; Pollard, & Johnston, 2001); Addenbrooke Cognitive Examination-III (ACE-III, Noone, 2015); Quality of Life (Control, Autonomy, Self-Realization, and Pleasure, CASP-12; Wiggins, Netuveli, Hyde, Higgs, & Blane, 2008); and a 12-month medical review which included weekly exercise frequency, BMI calculation, number of falls and hospital visits, and the amount of care received (in hours) on a weekly basis.

Data Analysis

A correlation analysis was performed between frailty and the candidate items to justify their inclusion into the COM-FI. Following this, a Cronbach's Alpha analysis was performed to assess the internal consistency of the model. Intra-class correlations were used to determine the test-retest reliability of the scale using frailty scores collected at baseline and 3 months.

To validate the COM-FI against Rockwood's (2005) criteria, a t-test was used to assess for a significant gender difference in frailty; correlation was performed to determine if a significant

relationship between frailty and age was present; and Cox regressions were performed to assess the prognostic capabilities of the COM-FI in determining if the model predicted risk of hospitalisation and death up to 2-years after their first assessment was completed. In cases where participants did not complete 2-years of assessments retirement village staff were contacted to provide an update if the participant was living or had died up until the 2-year point following their first assessment was reached.

As Holland *et al* (2015) found that the original COM-FI significantly predicted amount of formal care needed, to ensure this capability was not lost during the development process, a Cox Regression was also performed to determine if the developed COM-FI predicted need for formal care.

The impact of frailty progression on quality of life (Kojima *et al.*, 2016) and likelihood of a fall (Clegg *et al.*, 2013) is well established. This means if the COM-FI predicted both outcomes this would further support the notion the model is valid and reliable.

The sensitivity and specificity of the COM-FI predicting the need for care, having a fall, hospitalisation, and death was determined using Receiver Operating Curves.

With the exception of the intra-class correlation (which was conducted on participants who completed an assessment at both baseline and 3 months), and the Cox Regressions and Receiver Operating Curves (which both used all data points to assess prognostic validity), all analyses were performed using the participant's final assessment, so that attrition over the period did not affect the analyses.

Data was analysed using SPSS Version 25.

Results

Candidate Item Inclusion

Frailty scores gained from the COM-FI (with the 'falls' variable removed) were significantly negatively correlated with 'exercise frequency' ($r = -.431, p < .001$), and significantly positively correlated with 'polypharmacy' ($r = .379, p < .001$) and 'Coronary Heart Disease-Diabetes joint effect' ($r = .209, p < .001$). Therefore, Rockwood's (2005) item inclusion criteria

were met and the items were included into the COM-FI, producing a 52-item model (see Appendix One), which is used in the following analyses.

Descriptive Statistics

The number of participants, mean, and standard deviation of the variables: frailty, age, quality of life, care requirements, and number of falls and times hospitalised over the 12 months prior to assessment are displayed in Table 1. Quality of Life was added at a later point and so there are fewer people with that assessment, and numbers of falls and hospitalisation questions were not answered by all participants. Participant’s demographic data regarding sex, age, ethnicity, and socioeconomic status can be viewed in Appendix 2.

Table 1: A Table Displaying the Number of Participants, Mean, and Standard Deviation, of Participant Age, Frailty, and Outcomes.

| | | <i>n</i> | Mean | Std. Dev. |
|------------------|---|----------|-------|-----------|
| ExtraCare | Frailty (52-item) | 264 | .219 | .130 |
| | Age | 262 | 76.82 | 8.32 |
| | Quality of Life | 90 | 37.04 | 7.16 |
| | Care Received (Hours/Week) | 231 | 1.14 | 5.66 |
| | Number of Falls (previous 12 months) | 166 | .34 | 1.04 |
| | Hospitalisation (previous 12 months) | 176 | .61 | 1.86 |
| Community | Frailty (52-item) | 87 | .108 | .075 |
| | Age | 87 | 72.72 | 6.06 |
| | Quality of Life | 63 | 40.03 | 4.87 |
| | Care Received (Hours/Week) | 86 | 0 | 0 |
| | Number of Falls (previous 12 months) | 84 | .24 | 1.35 |
| | Hospitalisation (previous 12 months) | 85 | .09 | .29 |
| Total | Frailty (52-item) | 351 | .191 | .127 |
| | Age | 349 | 75.8 | 8.01 |
| | Quality of Life | 153 | 38.27 | 6.47 |
| | Care Received (Hours/Week) | 317 | .83 | 4.86 |
| | Number of Falls (previous 12 months) | 250 | .31 | 1.15 |
| | Hospitalisation (previous 12 months) | 261 | .441 | 1.55 |

Examination of Table 1 shows that participants in the ExtraCare cohort were both, on average, older and frailer when compared to the community cohort.

Test-Retest Reliability

A total of 164 participants had measures at baseline and 3 months. Test-retest reliability of the COM-FI was assessed using a two-way mixed-effects intra-class correlation with absolute agreement. The mean intra-class reliability (averaged across all items) was .910 (95% C.I. .875 - .935), indicating 'very good' to 'excellent' consistency between the frailty scores from the two assessments.

Internal Reliability

The Cronbach's Alpha score was .817, and the 'alpha if item deleted' scores ranged from .799 to .827, indicating high internal reliability with low risk of item redundancy (Pallant, 2011).

Concurrent Validity

There was no significant gender difference in frailty ($t = .876, p > .05$). However, there was a significant positive correlation between frailty and chronological age ($r = .232, p < .01$), and frailty significantly predicted quality of life ($R^2 = .409, F(1,151) = 104.6931, p < .001$).

Prognostic Validity

For the Cox Regressions, participant frailty scores were grouped into ranges of frailty to assess the increased risk of needing formal care, having a fall, being hospitalised, and dying within 2-years based on each participant's first frailty score. Participants with a frailty score above 0.5 were removed from the analysis as the sample for those respective groups was not sufficient to draw meaningful conclusions (eight persons). As predicting risk of death over a 2-year period requires at least two data collection points, only 246 participants were eligible for analysis. From the participants eligible for analysis, 40 received formal care, 104 had a fall, 79 had been hospitalised, and 19 died over the following two years from their first

assessment (a further breakdown of the percentage of participants in which the ‘event’ occurred based on their frailty category is provided in Appendix 3). Results are displayed in Table 2.

Table 2: Cox Regressions Assessing the Prognostic Capabilities of the COM-FI in Predicting Risk of Formal Care, Falls, Hospitalisation, and Death over a 2-Year Period.

| | Frailty Groups | n | B | SE | Wald | df | Sig. | Exp(B) | 95% CI | |
|-----------------|----------------|-----|--------|---------|--------|----|-------|--------|--------|---------|
| | | | | | | | | | Lower | Upper |
| Need Care | 0.0 - 0.1 | 95 | | | 51.042 | 4 | <.001 | | | |
| | 0.1 - 0.2 | 105 | 1.504 | 1.096 | 1.886 | 1 | .170 | 4.501 | .526 | 38.537 |
| | 0.2 - 0.3 | 65 | 2.513 | 1.061 | 5.611 | 1 | .018 | 12.344 | 1.543 | 98.752 |
| | 0.3 - 0.4 | 26 | 4.129 | 1.034 | 15.933 | 1 | <.001 | 62.119 | 8.179 | 471.781 |
| | 0.4 - 0.5 | 17 | 4.258 | 1.046 | 16.558 | 1 | <.001 | 70.686 | 9.090 | 549.666 |
| Death | 0.0 - 0.1 | 75 | | | 9.822 | 4 | .044 | | | |
| | 0.1 - 0.2 | 85 | 11.551 | 127.498 | .008 | 1 | .928 | --- | --- | --- |
| | 0.2 - 0.3 | 51 | 10.486 | 127.502 | .007 | 1 | .934 | --- | --- | --- |
| | 0.3 - 0.4 | 17 | 11.220 | 127.501 | .008 | 1 | .930 | --- | --- | --- |
| | 0.4 - 0.5 | 4 | 13.071 | 127.498 | .011 | 1 | .918 | --- | --- | --- |
| Falls | 0.0 - 0.1 | 102 | | | 17.793 | 4 | .001 | | | |
| | 0.1 - 0.2 | 116 | .542 | .287 | 3.572 | 1 | .059 | 1.719 | .980 | 3.015 |
| | 0.2 - 0.3 | 72 | .912 | .299 | 9.333 | 1 | .002 | 2.489 | 1.387 | 4.469 |
| | 0.3 - 0.4 | 30 | .909 | .381 | 5.690 | 1 | .017 | 2.482 | 1.176 | 5.237 |
| | 0.4 - 0.5 | 19 | 1.532 | .371 | 17.020 | 1 | <.001 | 4.628 | 2.235 | 9.583 |
| Hospitalisation | 0.0 - 0.1 | 95 | | | 18.415 | 4 | .001 | | | |
| | 0.1 - 0.2 | 108 | .570 | .255 | 5.011 | 1 | .025 | 1.768 | 1.073 | 2.912 |
| | 0.2 - 0.3 | 65 | .626 | .282 | 4.920 | 1 | .027 | 1.871 | 1.076 | 3.254 |
| | 0.3 - 0.4 | 26 | 1.306 | .313 | 17.372 | 1 | <.001 | 3.691 | 1.997 | 6.820 |
| | 0.4 - 0.5 | 18 | .866 | .390 | 4.926 | 1 | .026 | 2.378 | 1.107 | 5.109 |

With the exception of predicting death, the COM-FI significantly predicted all outcomes, with the frailest participants (0.4-0.5) being 70.69x more likely to need care, 4.63x more likely to have a fall, and 2.38x more likely to be hospitalised compared to the most robust participants.

Receiver Operating Curves

The area-under-the-curve (AUC), sensitivity and specificity in predicting the risk of needing care, having a falls, being hospitalised, and death are displayed in Table 3.

Table 3: Area under the Curve, Sensitivity and Specificity in Relation to the COM-FI Predicting Need for Care, Death, Falls, and Hospitalisation.

| | Sensitivity | Specificity | AUC | Std. Error | Sig. | 95% CI | |
|------------------------|-------------|-------------|------|------------|-------|--------|-------|
| | | | | | | Lower | Upper |
| Need Care | .850 | .728 | .869 | .032 | <.001 | .807 | .931 |
| Death | .684 | .628 | .773 | .047 | <.001 | .681 | .865 |
| Falls | .817 | .353 | .631 | .033 | <.001 | .567 | .695 |
| Hospitalisation | .792 | .365 | .614 | .033 | .001 | .550 | .678 |

Under the 'area' scoring criteria set by Maróco *et al* (2011), the COM-FI is a good model for predicting the need for care (as it scores above .800) and an acceptable model for predicting death, falls, and hospitalisation (scoring between .500 to .800). The sensitivity for all outcomes is acceptable (above .600), however the specificity for falls and hospitalisation is low (below .600), indicating a risk of false confirmation of these outcomes occurring.

Discussion

The purpose of this study was to develop and validate the frailty index designed by Holland *et al* (2015), known as the COM-FI, based on standard analytical methods, Rockwood's (2005) validation criteria, and findings from additional research (Clegg *et al.*, 2013; Holland *et al.*, 2015; Kojima *et al.*, 2016).

All candidate items were added into the COM-FI and falls was removed to be used as an outcome variable. Additionally, direction is offered for addressing the added vulnerability related to joint effects of specific co-morbidities.

With the exception of a gender difference and predicting death, all of Rockwood's (2005) validation criteria were met. Results also supported previous work as the updated COM-FI predicted need for formal care (Holland *et al.*, 2015), risk of having a fall (Clegg *et al.*, 2013), and quality of life (Kojima *et al.*, 2016) respectively. These findings further indicate the COM-FI possesses high levels of reliability and validity.

It is possible that the non-significant gender difference is due to a significant portion of the sample being recruited from retirement villages (74% of the sample), where residents are

generally frailer and live with more co-morbidities than age-matched people living in their original homes (Holland *et al.*, 2015). Being a specific population, there may be more men with higher levels of frailty than would normally be expected. This may also explain the relatively low relationship between frailty and age: according to Mitnitski *et al* (2005) residents of care institutions display a lower relationship between frailty and age because they are somewhat selected for frailty by the nature of their residence.

We can attribute the lack of prognostic capabilities using the Cox procedure in predicting death to the omission of participants with severe frailty scores. That is, the maximum frailty score used in the analysis was 0.5 (due to insufficient sample with a frailty score above 0.5), yet near end-of-life outcomes are attributed to frailty scores closer to 0.7. Therefore, to appropriately assess the prognostic capabilities of the Frailty Index using the Cox procedure, a larger sample with more people with severe frailty is required. Further analysis with this sample over a longer period, would also be useful. However, the area-under-the-curve for prediction of mortality was good, and comparable to other tools (e.g. SHARE FI; Theou, Brothers, Mitnitski, & Rockwood, 2013), and the COM-FI's more practical utility for planning care needs is evident.

Limitations

The low specificity of the COM-FI in predicting the risk of falls and hospitalisation indicates a level of risk of incorrectly identifying these outcomes as occurring. An important limitation is that the COM-FI, with 52 variables, is a time-consuming process, and requires variable reduction to improve usability and time efficiency. In addition, the use of an ExtraCare cohort which is, on average, frailer than community-dwelling individuals (Holland *et al.*, 2015; 2017; 2019) may produce a stronger association between frailty and outcomes considered in this study than if the sample consisted primarily of community-dwelling participants.

Conclusion

All candidate items considered for inclusion as part of the development process were justified. Proceeding from this, with the exception of gender differences and predicting mortality (albeit with specific population circumstances), all of Rockwood's (2005) validation

criteria were met. On this basis, it is reasonable to conclude that the COM-FI is a valid and reliable instrument for measuring frailty without the need for access to medical records and taking a more holistic approach, but there remains some scope for further improving the index for use in practice.

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