

HomeHealth SWAP statistical analysis plan

Exploring the impact of multiple long-term conditions on behaviour change within a service to maintain independence in older people with mild frailty

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Background

Many older people with mild to moderate frailty have multiple long term (health) conditions (MLTCs). Some of these are physical health related, others are mental health related.

This study will run within HomeHealth, utilising the same participants and data collected as part of the main trial¹.

Aims

To investigate how MLTCs interact with behaviour change approaches such as setting and achieving goals

To discover how MLTCs may impact on engagement with a health promotion service for older people with mild frailty

To explore the impact of MLTCs on the effectiveness of a behaviour change intervention in promoting independence, improving quality of life and reducing psychological distress.

To explore whether number of and type of MLTCs affect progress towards goals in a behaviour change intervention

To investigate if and how multiple long-term physical health conditions differ from those where a mental health condition is a comorbidity with regards to behaviour change techniques and outcomes

Timing of analysis

This analysis will take place after that of the main trial. The statisticians are likely to be unblinded by then. Additionally, no participants in the treatment as usual group will have had any HomeHealth appointments, so this will unblind/ confirm the identity of the randomised groups.

These results will be disseminated in a separate paper to the main HomeHealth clinical paper.

Data to be utilised in this study

- Cambridge multimorbidity score² using general weightings
- Type of long-term conditions from a list, coded into physical, mental or dementia
- Types of goals set, categorised into mobility, nutrition, psychological, social, cognitive, other
- Overall progress towards achieving goals using the average of the SMART goal progress score (0=no progress towards goal, 1=some progress towards goal, 2=goal fully met).

- Number of HomeHealth appointments attended/ intensity (attended at least three appointments versus less than three appointments)
- Mode of delivery (remote or face-to-face)
- Modified Barthel Index³ at baseline, 6 and 12 months
- Nottingham Extended Activities of Daily Living score (NEADL)⁴⁻⁶ at baseline, 6 and 12 months
- 12 item General Health Questionnaire score (GHQ-12)⁷ at baseline, 6 and 12 months
- EuroQol 5D-5L (EQ-5D-5L) utility at baseline, 6 and 12 months
- ICECAP-O tariff at baseline, 6 and 12 months
- Randomisation variable
- Site (3 categories)

Analysis

In those who were in the HomeHealth group, we will describe the types of goals set, overall progress towards achieving goals, appointment attendance/ intensity and mode of delivery (remote or face-to-face) using mean (SD) or median (IQR) for continuous variables depending on distribution and frequency (%) for categorical variables by number of long term conditions (0-1, 2-3, 4+) and in those with 2+ long term conditions by type of conditions (physical conditions only, ≥ 1 physical conditions + ≥ 1 mental health condition, and ≥ 1 physical condition + dementia).

Using both randomised groups, we will construct linear mixed models including the measures at 6 and 12 months in the outcomes (Barthel Index, NEADL, GHQ-12, EQ-5D-5L utilities, ICECAP-O tariffs). The models will include the baseline score of the outcome, site the stratification variable, 3 sites), Cambridge multimorbidity score, time, randomised group and an interaction between time and randomised group as fixed effects and participant as a random effect. A sensitivity analysis will replace the Cambridge multimorbidity score with number of long term conditions.

If there is sufficient power, we will consider, categorising the types of long-term conditions to less than two long term conditions, physical conditions only, ≥ 1 physical conditions + ≥ 1 mental health condition, and ≥ 1 physical condition + dementia, adding type of conditions to the linear mixed model described in the previous model in place of Cambridge multimorbidity score. We will also carry out similar analyses including number of physical conditions and number of mental health conditions.

References

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