Brief Title:	FrAilty Care and wEll-funcTion in Community Dwelling Older Adults (FACET)
Official Title:	Effect of Online Support and Patient Empowerment on Functional Ability and Well-being in Older Adults: a Pilot Study

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Method

Participants

Forty older adults (n-female: 6, n-male: 10, age: xx years, height: xx m, mass: xx kg), residing in the community and recruited via convenience sampling, participated in the study. Participants were excluded if they had moderate/severe dementia at baseline (defined as Mini Mental State Examination < 23), severe, disabling stroke at baseline within the previous 6 months (defined as new or previous stroke with Barthel Index < 9), or a recent (< 3 months prior randomisation) myocardial infarction, or unstable angina. In addition, participants were excluded if they were currently undergoing treatment that includes exercise and diet advice by health professionals and were referred at discharge for condition-specific rehabilitation (e.g. pulmonary rehabilitation, stroke rehabilitation) within the previous 6 months. The study received ethical approval from the University ethics committee and all participants were made aware of the nature of the study and their right to withdraw at any time, before providing written informed consent. All aspects of the study were conducted in accordance with the Declaration of Helsinki.

Procedures

The trial used a parallel-group design with four intervention arms in a two-by-two factorial design. Arms were based on the factors of 'consultation type' and 'intervention support' and consisted of professional led consultation with online support (PLOS), professional led consultation without online support (PLNS), participant empowered consultation with online support (PEOS) and participant empowered consultation without online support (PENS). Participants were randomly allocated to a group based on minimization for frailty status, age and gender.

Participants attended 2 visits prior to the intervention and 1 visits following the intervention. Various functional ability assessments and health related questionnaires were completed prior to the trial during visit 1 and 2 and repeated after 12-14 weeks during visit 3. During the second visit, participants received a consultation with advice on making lifestyle changes to promote healthy ageing. Between the first visit and second visit and a week before the third visit, participants collected 3 morning void urine samples at home for the determination of their nutritional status.

For PLOS and PLNS, the consultation was led by the professional and lifestyle recommendations were based on ViviFrail recommendations and personal experience. In contrast, during PEOS and PENS, the consultation was led by the participant, and started with the questions 'What matters to you', and 'What are your goals'. The professional based the lifestyle recommendations based on these responses.

For PLOS and PEOS, the 12-week intervention included access to an online monitoring platform. The online platform provided the lifestyle recommendations and consisted of a diary of activities, examples of exercises, general advice and instructions for monitoring and self-assessment. For PLNS and PENS, there was no access to the online monitoring platform, and lifestyle recommendations were provided on paper to the participant.

The consultation was based on the physical ability assessment, risk of falling, and completed questionnaires. Behaviour change advice as part of the lifestyle recommendations were derived from the COM-B model, which assumes that behaviour (B) is determined by capability (C), Opportunity (O)

and motivation (M). The capability was offered as feedback from the physical ability assessment and the motivation was assessed with the 'stages of change ladder'. The opportunities were in the form of personalized and individually tailored recommendations. Altogether, SMART goal setting and implementation intentions formed the methods of the lifestyle recommendations. The lifestyle recommendations made were recorded and included characteristics of type of exercises included (balance, strength, flexibility, multi-component, equipment used, nutrition, physical activity tasks), identified goals and action plans (frequency, duration, etc.).

Functional ability assessments performed prior and following the intervention consisted of the Short Physical Performance Battery (SPPB), timed-up-and-go (TUG), grip strength, usual walking speed, the 6 Minute Walk Test (6MWT), the sematic fluency test and body composition analysis. The SPPB consists of a scoring system based on the ability to complete 10 seconds of narrow, semi-tandem and tandem stance position while standing upright, the time taken to complete 5 chair rises at maximum speed, and usual walking speed. The TUG consists of the time taken using an accelerometer (G-Walk) to get up from a chair, walk around a cone 3 meters away and return to sit down and is performed at the participant's usual and comfortable speed. Grip strength was assessed as the maximal value obtained from three attempts with each hand using a dynamometer (Takei). Usual walking speed was determined over a distance of 8 meters, with timing gates placed 4 meters interspaced in the middle of the path. Spatio-temporal variables were derived from an accelerometer (G-walk) and consisted of stance duration, swing phase duration, step length and propulsion of right and left leg. The 6MWT consists of walking the further distance possible in 6 minutes around 2 cones places 10 meters apart. The SFT consists of the ability to mention as many words starting with a particular letter in one minute. Body composition analysis and bone mineral density assessment of the hip and spine was performed using whole-body DXA scanning (Hologic) to determine appendicular lean mass and body fat percentage, and body impedance analysis (BodyStat) to determine hydration status.

Health related questionnaires consisted of the Lawton-Brody and Barthel index to assess the level of abilities performed during daily living. Frailty was assessed using the FRAIL scale, the Frailty Trait scale and the frailty phenotype model. The frailty phenotype evaluation was derived from the usual walking speed, grip strength, a physical activity questionnaire and two questions related to the presence of unintentional weight loss and exhaustion. Physical activity levels were assessed with the CHAMPS. Well-being and quality of life were assessed with the WEMWBS, the SF-36 and EuroEQ-5d5L. Healthcare Resource Use was assessed during the 12-week intervention.

Nutritional status was assessed based on urine metabolomics, the Mini-Nutritional Assessment, the SNAQ and diet quality assessment. Urine was collected at home, using validated urine collection techniques to store and transport urine samples. Urine was collected at the 2nd and 3rd visit and stored in -80° until further analysis. Dried blood spot samples were collected at home using a Whatman Protein Saver Card to determine lipid levels. During the first visit, a finger prick blood spot sample was to determine Hba1C levels as an indicator of diabetes status, and assess LDL, HDL and total cholesterol.

Data analysis

All scores are standard derived from the tests itself, and data analyses processes have been published previously. Standard Operating Procedures are available upon request.

Statistical Analysis

Evaluation of the pilot consisted of the number of participants refusing to be allocated to their original group. If refused, participants were offered the alternative group ('cross-over'), but excluded from statistical analysis. Intervention recruitment, adherence (online platform usage, self-monitoring frequency, usage of support materials provided) and retention were considered sufficient if:

- with 3 participants per week (and relative to those screened, the consent rate taken into account),
- adherence to the intervention program exceeding 70% and
- 95% retained at follow up, respectively.

The lifestyle recommendations made were recorded for subsequent qualitative analyses and quantification of type of exercises included (balance, strength, flexibility, multi-component, equipment used, nutrition, physical activity tasks) as part of the pilot study evaluation.

Adverse event occurrence will be recorded. Protocol evaluation will consider time needed for the assessment and questionnaires and the consultation, support time needed for online monitoring and engagement during the intervention, to enable appropriate costing for future trials and revise accordingly. Participant characteristics (frailty, disability) will be summarized to determine future recruitment criteria.

Estimated sample size and confidence intervals will be initially based on primary outcome measures: Well-being (WEMWBS), Grip strength, Walking speed and SPPB. From those, but possible the secondary outcome measures, a primary outcome variable would be determined for the future randomized control trial.

Secondary outcome measures consist of:

- Functional ability performance, including timed-up-and-go, chair-stand test, balance, flexibility, 6MWT.
- Dietary analyses
- Healthcare Resource Use (i.e. hospital visits, GP appointments) assessed using a Healthcare Resource Use questionnaire at baseline and 12 weeks, to assess potential follow up impact due to inadvertent worrying of participants.
- Qualitative feedback from assessors and participants about FACET
  Quality of life derived from the Short Form 36 item health questionnaire (SF36) at baseline and 12 weeks, including the Physical Component Summary (PCS)