Building resilience and reversing frailty: a randomised controlled trial of a primary care intervention for older adults

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Abstract

Background

There is a need for effective primary care interventions that help older people combat frailty and build resilience.

Objective

To study the effectiveness of an optimised exercise and dietary protein intervention.

Design

Multicentre, randomised-controlled, parallel-arm trial.

Setting

Six primary care practices, Ireland.

Methods

Six general practitioners enrolled adults aged 65+ with Clinical Frailty Scale score ≤5 from December 2020 to May 2021. Participants were randomised to intervention or usual care with allocation concealed until enrolment. Intervention comprised a 3-month home-based exercise regime, emphasising strength, and dietary protein guidance (1.2 g/kg/day). Effectiveness was measured by comparing frailty levels, based on the SHARE-Frailty Instrument, on an intention-to-treat basis. Secondary outcomes included bone mass, muscle mass and biological age measured by bioelectrical impedance analysis. Ease of intervention and perceived health benefit were measured on Likert scales.

Results

Of the 359 adults screened, 197 were eligible and 168 enrolled; 156 (92.9%) attended follow-up (mean age 77.1; 67.3% women; 79 intervention, 77 control). At baseline, 17.7% of intervention and 16.9% of control participants were frail by SHARE-FI. At follow-up, 6.3 and 18.2% were frail, respectively. The odds ratio of being frail between

intervention and control groups post-intervention was 0.23 (95% confidence interval: 0.07–0.72; $P = 0.011$), adjusting for age, gender and site. Absolute risk reduction was 11.9% (CI: 0.8%–22.9%). Number needed to treat was 8.4. Grip strength ($P < 0.001$) and bone mass ($P = 0.040$) improved significantly. 66.2% found the intervention easy, 69.0% reported feeling better.

Conclusion

A combination of exercises and dietary protein significantly reduced frailty and improved self-reported health.

Key Points

- In primary care, there is a need to provide person-centred interventions that help older people combat frailty and build resilience, but evidence is lacking especially in those who have pre-frailty or mild frailty.
- We conducted a randomised controlled trial to measure effectiveness of an intervention of exercises, emphasising strength, and dietary protein in six primary care practices in Ireland.
- The intervention significantly reduced frailty and most participants reported that the intervention was easy and improved their health.

Introduction

Frailty in older people is a state of physical vulnerability to external stressors that is associated with increased risk of disability, dependency and mortality [1, 2]. At the opposing end of the biological health spectrum lies resilience [3], which is the capacity to withstand stressors [4]. Frailty poses multiple challenges in ageing societies. Prevalence of frailty increases with age from 11% in over 65-year-olds to 50% in over 80-year-olds [5]. Mortality risk is almost three times higher for frail compared with non-frail older people [6]. The additional annual healthcare cost associated with frailty can be up to €12,000 per person [7, 8] and an older person living with frailty may visit their general practitioner (GP) on up to four more occasions annually than a non-frail person [9].

Population-based longitudinal studies have shown that bidirectional transitions between states of frailty are frequent [10, 11]. There is evidence that frailty can be delayed and even reversed with appropriate interventions [12–14]. However, interventions remain underused in primary care [15]. This may in part be due to the absence of a standard approach to frailty intervention [12, 16]. Furthermore, older people tend to perceive frailty negatively [17, 18], believing it is inevitable or unmodifiable [19]. Intervention acceptability and effectiveness may consequently be affected [19]. Resilience, on the other hand, is viewed as a positive attribute [20].

In primary care, frailty can be operationally defined by Fried's phenotype model [21], with 'frail' meeting at least three and 'pre-frail' meeting one or two of the following criteria: low grip strength, low energy, slow walking speed, low physical activity and unintentional weight loss. This definition has been adapted to provide a continuous score using the SHARE-Frailty Instrument (SHARE-FI) [22]. While the phenotypical approach to frailty captures a pre-disability state [23], the Clinical Frailty Scale (CFS) [24, 25] was developed as a clinical judgement-based measure that can capture higher levels of disability where help with all activities of daily living is required (i.e. CFS > 5). In England, it has been estimated that 17.2% of adults registered in primary care have a physical disability [26]. Therefore, a pre-disability model of frailty may be suited for primary care, as it captures clients at an earlier stage of the disabling process where interventions can be more preventative, and offers more quantitative measurement of intervention effectiveness [27]. CFS remains useful for rapid eligibility screening.

There is a need to provide person-centred interventions for older people in combatting frailty and building resilience in primary care, but evidence is lacking in those who have pre-frailty or mild frailty [28]. We identified a broad heterogeneity of interventions and variable effectiveness when assessing 925 studies in a systematic review of primary care frailty interventions [12]. Interventions included diverse physical exercises, health education, nutritional supplements, medication management, home visits,

comprehensive geriatric assessment, hormone supplementation and counselling. The most effective and easiest to implement intervention may be a combination of exercises emphasising weight-bearing for strength and sufficient dietary protein, though a definitive approach has yet to be identified [12, 13]. No previous trial appeared to have undertaken prior feasibility assessment and public and patient involvement (PPI) was lacking. We co-designed an intervention of exercise and dietary protein education, optimised through our systematic review [12], meta-analysis [13], PPI [29] and feasibility assessment [30]. We aimed to study the effectiveness of a definitive intervention in a randomised controlled trial (RCT) in six primary care practices in Ireland.

Methods

Design

This multicentred, randomised controlled, parallel arm trial measured effectiveness of a primary care intervention to reverse frailty and build resilience versus usual care, among adults aged 65 and over at 3-month follow-up.

The intervention was co-designed with 112 older people through PPI over 12 months [29]. A total of 18 over 65-year-olds helped co-design an exercise regime in two group discussions [31] using the Socratic method [32], 94 contributed intervention feedback in one-on-one telephone interviews and 10 refined the intervention in three online workshops.

Feasibility of the exercise component was assessed in a study with 94 older people [30]. We applied the Bowen feasibility model [33], testing: acceptability; demand; implementation; practicality; adaptation; integration; expansion and limited-efficacy. A randomised follow-up telephone call, appearing to help increase adherence by 20% ($P = 0.031$), was included for all participants in the RCT [30].

A protocol was published [34] and the trial registered at ClinicalTrials.gov (ID NCT04628754, 13 November 2020). Trial enrolment took place over 5 months from December 2020.

Participants

All older adults presenting to GP site-investigators at six primary care practices were screened for eligibility by the GP. Inclusion criteria: aged 65 or older; Clinical Frailty Scale score ≤5 (i.e. mildly frail or less) [25]. Exclusion criteria: end-of-life care; persons in nursing-home care; concurrent malignancy; chronic kidney disease stage 3 or 4; baseline Montreal Cognitive Assessment (MoCA) score ≤10 or diagnosis of dementia; persons with emergency care needs.

Eligible adults were offered information about the study by the GP. If interested, they were offered an information leaflet, invited to ask any questions and provide informed consent [35].

Randomisation and masking

Participants were randomly assigned to intervention or usual care parallel arms on a 1:1 basis. The sequence was generated using the US National Cancer Institute randomisation tool [36]. Allocation was concealed until a participant had consented to enrolment with a GP, who then assigned them and provided the intervention or usual care. Allocation was not masked to participants or GPs. Baseline measurements of age, gender, CFS and SHARE-FI were undertaken before randomisation, while smoking history, alcohol intake, education, co-morbidities and body composition, including bone and muscle mass, were recorded after randomisation. A blinded assessor measured four self-reported frailty components and the GP measured handgrip strength.

Intervention

GP site-investigators who delivered the intervention participated in three pre-enrolment training sessions and subsequent monthly meetings, led by the principal investigator.

Intervention participants were provided a leaflet with photographic overview of a home-based exercise regime and GP demonstration of key exercises. They were provided with written and pictorial information on post-exercise protein consumption as part of a balanced diet. Participants assigned to the usual care group received normal primary care. The delivery of patient training by the GP took no more than 5 min (net of data gathering), face-to-face in the GP's surgery room. Participants were encouraged to spend at least 3 h and up to 5 h per week exercising and walking.

The resistance exercise regime consisted of 10 physical exercises, repeated 10 times, increased to 15 repetitions when comfortable. Exercises were to be undertaken at least four times per week, up to once daily. Participants were asked to walk for 30 to 45 min, three to four times weekly. Participants were advised to consume 1.2 g protein per kg body weight daily [37]. The leaflet included information on sources of protein, including plant-based, and timing of consumption. Intervention leaflets are shown in Supplementary Figures S1–S3. The marginal cost of printing was €0.1 per intervention.

Intervention participants were telephoned by the GP after 1 month and 3 months and asked set questions about adherence, ease of the intervention and whether they had noticed difference to general health as a result of the intervention. Participants attended at 3 months for health and frailty measurements. Supplementary Table S1 shows the schedule of events.

Measures

Handgrip strength was measured using a Constant dynamometer. Bioelectrical impedance analysis (BIA) was recorded using a Tanita RD545 Body Composition Analyser. Biological age is base metabolic rate (BMR)

compared with same age averages [38]. Higher muscle mass and lower body fat increase BMR and lower biological age.

Content:	Assessments:
Primary outcome	The percentage of participants that are frail in each trial arm, measured by SHARE-FI [22] at 3 months. SHARE-FI is an open-access validated, gender-specific phenotypical frailty tool based on exhaustion, loss of appetite, handgrip strength, functional difficulties (walking 100 m or climbing one flight of stairs without resting) and low physical activity. SHARE-FI continuous score is divided into categories for frailty classification: for females, scores <0.315 indicate non-frail, 0.316 to 2.130 are pre-frail and > 2.131 are frail. For males, scores <1.211 indicate non-frail, 1.212 to 3.005 are pre-frail and > 3.006 are frail. SHARE-FI was chosen as the preferred tool due to its advantages as a pragmatic, quantitative measurement, designed for primary care compared with: (1) CFS, which is useful for rapid frailty assessment and eligibility screening, as applied in this RCT, but is more subjective and not specifically designed for primary care; (2) the Fried tool, which requires reference to population values for quintile measurement and stratification that may not be available, as well as floorspace/distance for walking speed measurement that is not available or practical in all primary care settings; (3) Frailty index tools based on the cumulative deficit model proposed by Rockwood and Mitnitski, which also require population quartile data and lengthy health-deficit lists; (4) FRAIL scale, which is practical to use in primary care but lacks an objective, quantitative measure, such as grip strength.
Secondary outcomes	(1) Muscle mass, bone mass, body fat and biological age by BIA. (2) Ease of the intervention on a five-point Likert scale: ‘very easy’, ‘somewhat easy’, ‘neither easy nor hard’, ‘somewhat hard’, ‘very hard’. (3) Difference to general health on a five-point Likert scale: ‘much better’, ‘slightly better’, ‘about the same’, ‘slightly worse’, ‘much worse’.
Intervention fidelity	To maximise internal validity [39], the intervention and control groups received instructions exactly as described in the study protocol [34].

Statistical analysis

Sample size

We estimated a minimum sample size of 176 based on: two independent study groups; improvement of frailty status in the intervention group from frail to pre-frail or non-frail of 15% (informed by a previous Irish population-based observational study of frailty phenotype transitions showing the probability of transition from frail to non-frail was 6%, and from pre-frail to non-frail 32%, averaging 19% over a longer 2-year period [10]); allowing for 3% control group improvement due to performance bias; enrolment ratio of 1; 5% probability of type I error; 80% power. We set an overall target of 210 to allow for 15% loss to follow-up.

Data analysis

Statistical analyses were carried out using Stata software (version 14). Descriptive statistics were given as mean with standard deviation (SD), median with interquartile range (IQR) or count with percentage (%). Age, gender and site were adjusted for when comparing outcomes between trial arms; 95% confidence intervals (CI) and *P* values were reported for endpoints.

Primary analysis

Differences in proportions of SHARE-FI frailty were analysed between groups at 3 months using logistic regression and reported as an odds ratio (OR), adjusting for age, gender and site.

Secondary analysis

BIA measurements at 3 months were analysed using a linear mixed effects regression model. Chi-squared tests assessed differences for ease of the intervention and general health in the treatment group only, followed by binomial tests with multiple comparison controlled for with the Bonferroni correction method to determine where differences existed.

Analyses were conducted on an intention-to-treat basis, which included intervention participants attending follow-up who had not adhered to the intervention (Figure 1).

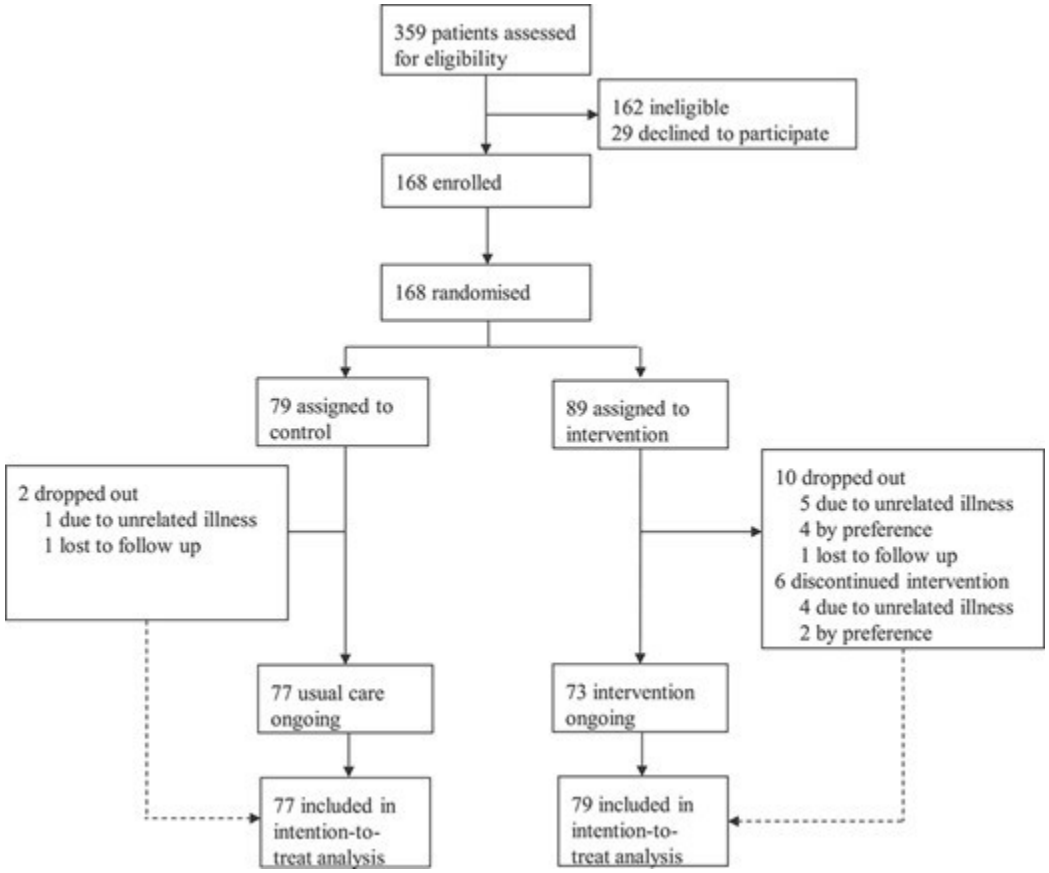

Figure 1

Trial profile.

Table 1: Baseline characteristics for control and intervention groups									
	Control				**Intervention**				**P**
	Mean (SD)	Median (IQR)	Number (%)	n	Mean (SD)	Median (IQR)	Number (%)	n	
Age in years (SD)	76.5 (5.2)	77.0 (7.0)		77	77.6 (5.2)	77.0 (7.0)		79	0.218[b]
Female gender (%)			51 (66.2)	77			54 (68.3)	79	0.777[a]
Living with someone, 'yes' (%)			53 (69.7)	76			57 (72.1)	79	0.741[a]
Smoking history, 'yes' (%)			18 (23.4)	77			30 (38.0)	79	0.048[a]
Drinks alcohol , 'yes' (%)			47 (61.8)	76			47 (61.0)	77	0.919[a]
Third level education, 'yes' (%)			25 (35.2)	71			28 (37.8)	74	0.927[a]
Number co-morbidities	3.4 (1.7)			63	3.1 (2.1)			61	0.231[c]
BMI (SD)	27.4 (5.2)	26.6 (6.8)		77	28.1 (5.3)	28.1 (6.9)		79	0.280[c]
Frail (%)			13 (16.9)	77			14 (17.7)	79	
Pre-frail (%)			34 (44.2)	77			37 (46.8)	79	0.902[a]
Non-frail (%)			30 (39.0)	77			28 (35.4)	79	
SHARE-FI (SD)	1.0 (1.3)	0.7 (1.8)		77	1.1 (1.4)	0.9 (2.0)		79	0.588[c]
Grip strength (kg) (SD)	22.3 (7.4)	21.0 (9.5)		77	22.4 (7.4)	22.0 (8.9)		79	0.803[c]
Exhaustion (0/1)			0.51	77			0.52	79	0.876[a]
Appetite loss (0/1)			0.12	77			0.15	79	0.522[a]
Slowness (0/1)			0.38	77			0.35	79	0.774[a]
Activity 1 (>1/week) (%)			55 (71.4)	77			44 (55.7)	79	
Activity 2 (1/week) (%)			13 (16.9)	77			15 (19.0)	79	0.137[a]
Activity 3 (1-3/month) (%)			7 (9.1)	77			16 (20.3)	79	
Activity 4 (hardly/ never) (%)			2 (2.6)	77			4 (5.0)	79	
CFS									
CFS 1 (%)			0 (0.0)	77			1 (1.3)	79	
CFS 2 (%)			12 (15.6)	77			6 (7.6)	79	
CFS 3 (%)			28 (36.4)	77			30 (38.0)	79	0.359[a]
CFS 4 (%)			30 (38.9)	77			30 (38.0)	79	
CFS 5 (%)			7 (9.1)	77			12 (15.1)	79	
Muscle mass (kg) (SD)	43.7 (10.6)	41.2 (17.1)		75	43.9 (8.9)	41.5 (12.5)		73	0.691[c]
Bone mass (kg) (SD)	2.3 (0.5)	2.2 (0.9)		75	2.3 (0.4)	2.2 (0.7)		73	0.726[c]
Body fat (SD)	37.1 (8.8)	34.9 (10.7)		75	38.2 (10.0)	38.0 (13.0)		73	0.427[c]
Biological age (SD)	73.6 (11.7)	73.0 (21.0)		69	74.7 (11.9)	73.0 (21.0)		65	0.499[c]

[a] Chi-squared test, [b] independent t-test, [c] Mann Whitney U

Results

A total of 359 older adults, presenting to six primary care practices, from December 2020 to May 2021, were assessed and 197 (54.9%) met the eligibility criteria; 168 (85.3%) were recruited; 156 (92.9%) completed follow-up: 79 in the intervention group and 77 in the control group; 105 (67.3%) were female and the mean age was 77.1 years (SD 5.2). Of the 12 (7.1%) participants who dropped out (five female (41.7%)), six cited unrelated illness, four preferred to withdraw and two were lost to follow-up (Figure 1). There were no significant differences in baseline characteristics between control and intervention groups (Table 1).

The risk of being frail at 3 months was significantly reduced in the intervention group relative to the control group (OR 0.23, 95% CI: 0.07–0.72; $P = 0.011$), adjusting for age, gender and site (Table 2, Figure 2). The absolute risk reduction (ARR) was 11.9% (95% CI: 0.8%–22.9%) and number needed to treat (NNT) was 8.4; 17.7% of intervention and 16.9% of control participants were frail at baseline; 6.3% and 18.2% were frail, respectively, at follow-up.

Grip strength improved in the intervention group compared with the control group, with adjusted difference in means of 1.8 kg (95% CI: 0.84–2.71; $P < 0.001$) (Supplementary Figure S4). There were also significant improvements in activity level ($P = 0.008$) and slowness ($P = 0.014$) in the intervention group compared with the control group.

An increase in bone mass in the intervention group compared with the control group was significant (0.05; 95% CI: 0.00–0.09; $P = 0.040$). Muscle mass, body fat and biological age improved in the intervention group compared to the control group though not statistically significantly (Table 2).

A total of 65 intervention participants (82.3%) reported good adherence to both exercising and protein intake at the 1-month call (exercising on

average 4.1 times per week), and 73 (92.4%) reported good adherence at 3 months, following the check in call (exercising on average 4.0 times per week).

66.2% of participants reported the intervention being easy or very easy to undertake. In a separate analysis, 69.0% reported feeling better as a result of the intervention. Chi-squared tests confirmed statistical differences in perceptions in both questions ($P < 0.001$) (Figure 3).

No adverse events were recorded.

Table 2: Frailty and other health indicators at three month follow-up

	Control				Intervention				Adjusted intervention effect*	
	Mean (SD)	Median (IQR)	Number (%)	n	Mean (SD)	Median (IQR)	Number (%)	n	OR (95% CI)[a] or Reg coeff (95% CI)[b]	P
Frail (%)			14 (18.2)	77			5 (6.3)	97	0.23 (0.07 to 0.72) [a1]	**0.011**
Pre-frail (%)			21 (27.3)	77			20 (25.3)	97	0.43 (0.22 to 0.84) [a2]	**0.014**
Non-frail (%)			42 (54.5)	77			54 (68.3)	97	2.17 (1.07 to 4.39) [a3]	**0.032**
SHARE-FI	0.85 (1.3)	0.46 (2.0)		77	0.23 (1.0)	-0.10 (1.2)		97	-0.70 (-1.06 to -0.34)[b]	**<0.001**
Grip strength (kg)	21.6 (7.7)	20.2 (9.6)		77	23.5 (7.7)	22.1 (7.8)		97	2.40 (0.74 to 4.04) [b]	**0.005**
Exhaustion (0/1)			0.42	77			0.32	97	0.58 (0.29 to 1.17) [a]	0.128
Appetite loss (0/1)			0.20	77			0.09	97	0.39 (0.15 to 1.02) [a]	0.054
Slowness (0/1)			0.30	77			0.18	97	0.35 (0.15 to 0.81) [a]	**0.014**
Activity 1 (>1/week) (%)			60 (78.9)	67			73 (92.4)	97		
Activity 2 (1/week) (%)			12 (15.8)	67			4 (5.1)	97	0.23 (0.08 to 0.68) [a]	**0.008**
Activity 3 (1-3/month) (%)			4 (5.3)	67			2 (2.5)	97		
Activity 4 (hardly/never) (%)			0 (0.0)	67			0 (0.0)	97		
Change in muscle mass (kg)	0.4 (2.7)	0.2 (1.8)		37	0.5 (2.0)	0.4 (1.3)		07	0.15 (-0.65 to 0.95) [b]	0.710
Change in body fat (kg)	0.4 (2.7)	0.3 (3.5)		57	1.3 (8.0)	0.9 (1.3)		16	-0.73 (-2.66 to 1.20) [b]	0.457
Change in bone mass (kg)	0.0 (0.1)	0.0 (0.1)		56	0.1 (0.2)	0.0 (0.1)		96	0.05 (0.00 to 0.09) [b]	**0.040**
Change in biological age (yrs)	0.3 (4.1)	0.0 (1.0)		69	-0.6 (3.8)	0.0 (2.0)		62	-0.86 (-2.22 to 0.51) [b]	0.217

Change in grip strength (kg)	-0.8 (2.7)	-0.8 (2.7)	7 7	1.0 (3.2)	1.1 (3.9)	7 9	1.78 (0.84 to 2.71) [b]	**<0.001**

* Adjusted for age, gender, site. Reg coeff = regression coefficient. [1] OR of being frail in the intervention group was 0.23 times that of control group. [2] OR for improvement of frailty
status in any category in the intervention group was 0.43 times that of the control group. [3] OR of being non-frail in the intervention group was 2.17 times that of the control group

* Adjusted for age, gender, site. Reg coeff = regression coefficient [1]. Odds of being frail for the intervention group were 0.23 times that of control group.

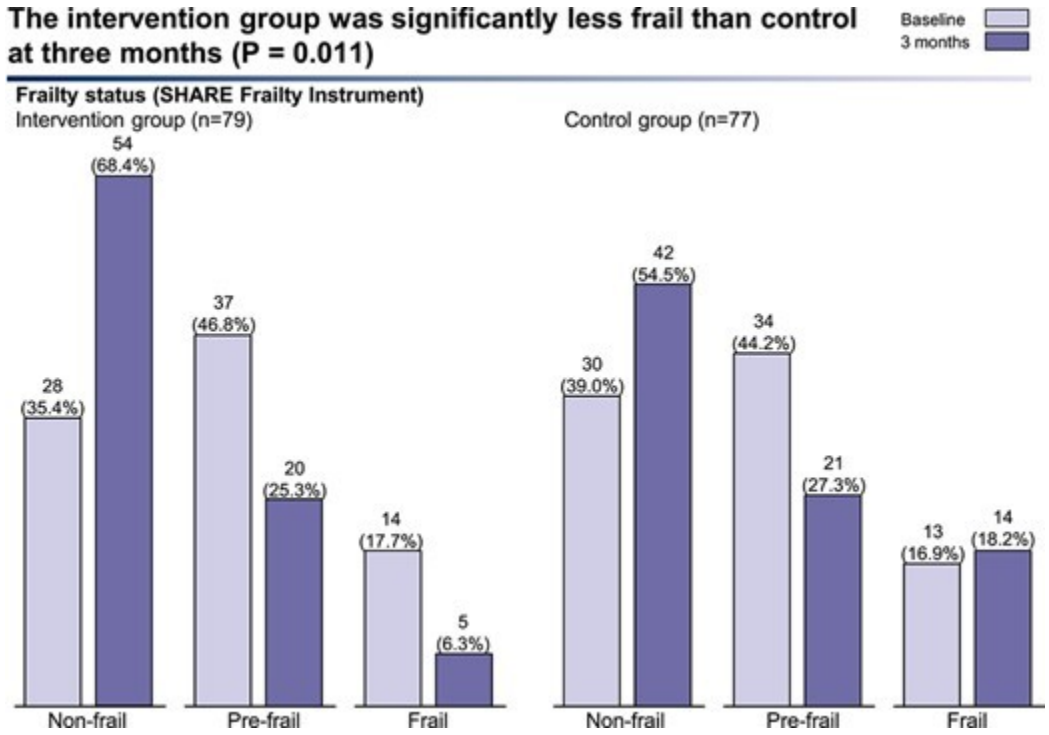

Figure 2

Frailty status of groups at baseline and 3 months.

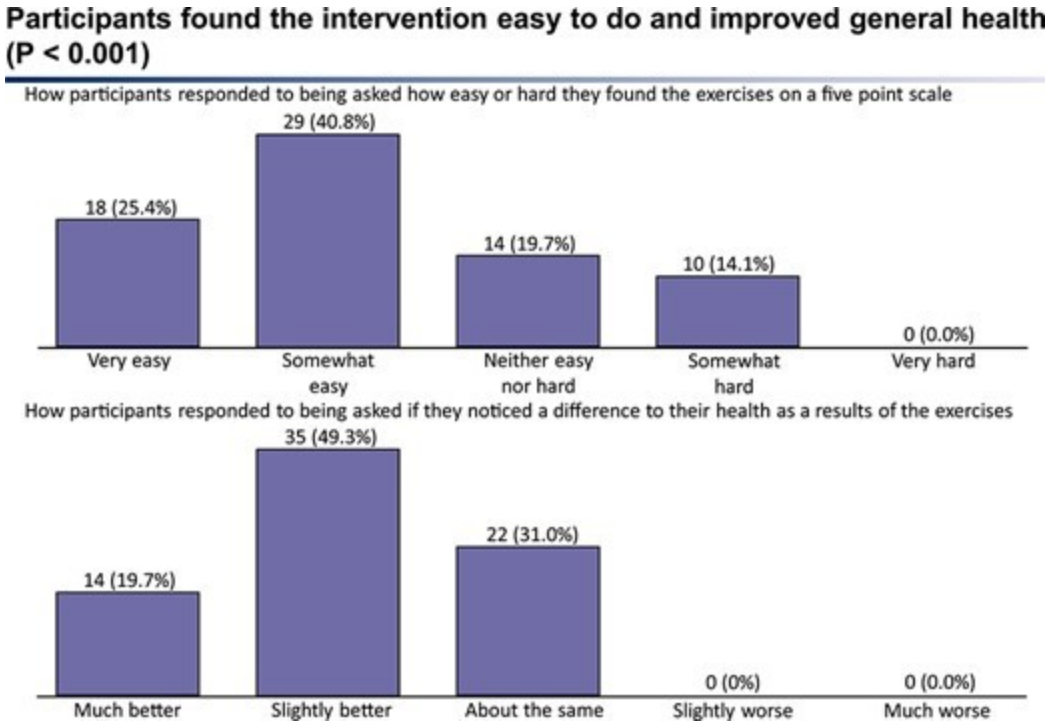

Figure 3

Participant ratings of ease of intervention and difference to general health.

Discussion

Summary

An intervention of physical activity and protein intake guidance led to significant improvements in frailty status, grip strength, activity level, slowness and bone mass at three months. The number of frail participants in the intervention group decreased by two-thirds.

Strengths and limitations

This study reports a feasible, effective intervention to reverse frailty and build resilience where evidence was previously lacking. The intervention was optimised by PPI and prior feasibility assessment. Meaningful PPI co-design with 112 older people ensured their preferences and needs were central to the intervention and contributed to high rates of participation and adherence. To the best of our knowledge, it is the first frailty and resilience study to measure muscle mass, bone mass, body fat and biological age using the BIA technology.

In terms of weaknesses, inclusion was limited to participants with a CFS score ≤5 (‘mildly frail’ or less), limiting generalisability to more severe frailty. It remains to be assessed if older people with higher frailty levels, including more severe disability, could benefit from a similar programme.

As an open label study, this trial risked introducing selection and participant bias. This limitation was mitigated by applying eligibility criteria to every consecutive patient who presented. Site-investigators were also blinded to control/intervention until the participant had committed. A blinded investigator called participants to measure self-reported SHARE-FI components.

Activity level is one of the five SHARE-FI measurements and an intervention that includes activity risks affecting the outcome. However, the outcome result remained statistically significant when the activity level measure was not included.

We gathered qualitative feedback from participants in a way that was feasible for primary care interactions but a limitation is that these were not validated measures of self-rated health or health-related quality of life, such as EQ-5D [41].

BIA accuracy is in line with gold standard measurements such as DXA [42]. However, BIA limitations include reduced absolute accuracy for people with BMI >34 [43]. There were 14 (9.0%) such participants in this study. Dehydration may cause underestimation of fat-free mass [44]. This limitation of single measurements is mitigated as BIA remains acceptable for monitoring body changes over time [45].

Comparison with existing literature

We built on a platform of 46 diverse primary care frailty interventions assessed in our systematic review and achieved greater efficacy with this optimised intervention [12]. Six studies involved strength exercises. Seven involved protein supplementation. Only one study used strength exercises and protein (Seino 2017) [46], while one trialled mixed exercises, including strength, and nutritional assessment (Serra-Prat 2017) [1]. Serra-Prat's intervention appeared the most effective among the other studies assessed. Findings were comparable with this study with 15.3% of control group participants progressing to frailty after 1 year, and 4.9% undertaking exercises progressing to frailty (OR 0.29). Our study demonstrated results in a shorter period of time. Other studies involved health education, hormone supplementation, home visits and counselling. We could not identify PPI or prior feasibility assessment in other studies. Ours is the first study to temper the often negative connotations of frailty with the positive language of resilience in participant engagement.

Implications for research and practice

Our study outlines an effective and feasible intervention that GPs can offer older people to combat frailty and build resilience.

Mandatory frailty screening has been introduced in some countries, such as England, yet guidance on interventions to address frailty is lacking. This study can contribute to a growing body of evidence on effective interventions.

Further research is warranted to assess long-term intervention impact, adherence and cost effectiveness. Further research would be welcome on how to enhance such interventions with increased social interaction, which has been shown to be a factor in reducing the risk of frailty [47, 48]. Research would be helpful on how commonly used activity trackers might improve objective frailty measurement as well as support motivation and individual empowerment [49].

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Ethical Approval

The Irish College of General Practitioners approved the study on 3 November 2020 (ICGP_REC_20_0023).

Declaration of Conflicts of Interest

None.

Declaration of Sources of Funding

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Data Availability

The study protocol is available at: the HRB Open Research repository: https://hrbopenresearch.org/articles/3-91. A model consent form is available at the Harvard Dataverse repository: https://doi.org/10.7910/DVN/RKEGIV. The anonymized study data are available on request from the corresponding author.

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