Study Title: Feasibility study to test the implementation of Health promotion advice (exercise and protein intake) for older people attending a community mental health service

Short title: Brief health promotion intervention for older people in mental health services

Date September 25 2023

NCT number (not available yet)

Background

Frailty is an age-related syndrome and describes the condition of older people's increased risk of adverse health outcomes, such as falls, institutionalization, hospitalization, disability and death. From The Irish Longitudinal study on Aging (TILDA) the prevalence of frailty in community dwelling adults aged 50 years and over in Ireland was 12.7% and the prevalence of pre-frailty was 31%. In people aged 65 year and over, the prevalence increased to 21.5% and 40% for pre-frailty.

In older people living with enduring or new onset mental health conditions, a recent systematic review suggested the prevalence of frailty in older people living with severe mental illness between 10.2 and 89.7% and was high in comparison to the general population (Pearson et al 2022). individuals with a mental disorder had greater all-cause mortality hazards than the comparison group without mental disorders. The highest hazard ratio (3.65, 95% CI 2.40-5.54) was observed among individuals with bipolar disorder and frailty, relative to non-frail individuals without mental disorders.

Mental health is defined as a "state of well-being in which the individual realises his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community" (WHO, 2001). Mental illness is described as the loss of mental health due to a mental disorder. The Mental Health Act 2001 defines mental illness as ''a state of mind of a person which affects the person's thinking, perceiving, emotion or judgment and which seriously impairs the mental function of the person to the extent that he or she requires care or medical treatment in his or her own interest or in the interest of other persons" (Government of Ireland 2001, pg.10). The Older Adult mental health service cares for and provides treatment for new onset functional mental illness and dementia with complex behaviours for persons over the age of 65 years.

TILDA found frailty to have a bi directional relationship with mental health and older adults. People living with frailty are more likely to experience decline in mental health, lowering cognitive function and an increase in depressive symptoms. While people who live with enduring mental health may experience accelerated ageing and frailty due to mental distress and prolonged medication use or substance abuse.

There is a strong evidence base for reversal of frailty in the general population (Reference systematic reviews), interventions focus on exercise with or without protein based nutrition. However, there is very few studies that have translated this research to older peoples living with severe mental illness.

A recent RCT undertaken in Irish GP practices identified the acceptability and effectiveness of a low intensity intervention combining brief (<10 mins) advice on exercise and nutrition as with supporting information leaflets were acceptable to older people and helped to improve functional performance (Travers et al 2020). (Appendix 1 exercise and nutrition leaflets).

In mental health consultations, advice on exercise and nutrition is often provided mental well-being benefits but it is not discussed in relation to building resilience and preventing frailty (Traver et al In press).

In this study we aim to test the acceptability and feasibility of replicating the above intervention for older patients attending MH consultations with the candidate ANP [AK].

Aim

The aim of this study is to test the delivery of brief health promotion advice with supporting information leaflets as part of standard clinical consultation for older people attending a community mental health service.

Objectives: The main objectives are to;

(a) to screen MH patients for frailty using validated tools the clinical frailty scale and SCAR-F
(b) to test the feasibility of patient recruitment and data collection in the target population
(c) determine the prevalence of frailty in older adults living with a mental health condition within an outpatient MH service
(d) examine the acceptability of the brief health promotion advice and information leaflets as part of MH consultation
(e) examine self-reported adherence to the exercise and nutrition advice at 1 and 3-month follow-up
(f) Repeat frailty screening and overall physical and mental health at three month follow-up

Target Population

The target population is older adults attending mental health service aged 65 years and older. Age 65 years is the age for referral to the older adult mental health services. The Older adult mental health services provide care and treatment for people aged over 65's who develop new onset functional mental illness such as depression, severe anxiety or those with a diagnosis of dementia with behavioral and psychological problems requiring specialist intervention and care.

Patients with stable mental health conditions (during a recovery phase) will be identified form community mental health clinics and ANP community case load

Sample size

We aim to recruit 15-20 patients to test the feasibility of the intervention in this population.

Inclusion criteria

For the purpose of this study service users eligible for the study are:

(a) Aged 65 years and older

(b) Cognitive capacity to provide informed consent
(c) Attending Older adult mental health services
(d) MH team deem client stable and able to participate in intervention
(e) Patient independently mobile and living in the community (may use a walk aid)(Clinical frailty Scale ≤5)

Exclusion Criteria

For the purpose of this study

(a) Service users with moderate advanced dementia will be excluded as the intervention is unsupervised.
(b) Patents who cannot provide informed consent
(c) Patients that cannot understand English or require a translator
(d) Patients experience acute mental health crisis
(e) Patients with significant restricted mobility, using Zimmer frame inside or outside their house (CFS≥5)

Study Design

The study uses a one group pretest –posttest intervention design with patient survey at baseline, 1 month and 3 month follow-up. The project is undertaken over 12 months. Once ethical approval is obtained, patient recruitment and baseline data is collected and the intervention delivered: in March – June 2023, 1 month follow-up April to July and three month follow-up August to October 2023.

Intervention components

The intervention is delivered by the candidate ANP who is an experienced mental health nurse and is skilled in using motivational interviewing principles to support behaviour change. A normal part of the role is the provision of general health promotion advice for patients in clinics and their home. This aligns with the HSE policy on Making Every Contact Count (https://www.hse.ie/eng/about/who/healthwellbeing/making-every-contact-count/).

- Deliver brief Health Promotion advice on exercise and protein nutrition for muscle health to promote resilience and reduce risk of frailty
- Provide patients with information leaflets and clarify expectations for frequency of exercise (Appendix). The exercise and nutrition advise leaflets are used with permission of Travers et al 2022. Both leaflets were deigned based on extensive public patient involvement with older patients, physiotherapist and dietician. The exercises are low risk (use a chair for balance support, sit to stand exercises). Patients with impaired mobility, using Zimmer frame are excluded from study.
- One-month follow-up is undertaken via telephone (or face-to-face if visit scheduled as part of routine care). The one-month follow-up is to encourage adherence to

exercise and nutrition advice and examine adherence and feasibility of undertaking exercise and following diet advice.

Data collection

The ANP completes the structured questionnaire with the patient in the MH clinic or patient home during routine clinical consultations. The one-month and three month follow-up via telephone or in the OPD clinic/persons' home as part of normal schedule of visits. No extra clinic or home visits are planned as part of the study.

The structured questionnaire used in this study has been developed by an expert group of geriatricians, and old age psychiatry and includes validated measures of frailty (see below)

This study tests the user acceptability of the intervention and the recruitment and data collection approach.

Ethical approval was obtained from Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC)

Obtaining Consent

Participants provide written consent to the study. the ANP liaises with the Mental Health team to identify eligible patients and ensure the team are happy for the service user to be approached about the study.

Service Users receive an introduction letter and a copy of the patient information sheet informing them of the study and advising that they may be asked to participate in the study at their next outpatient appointment or home visit. The patient meets the data collector who explains the study, answer any questions and obtains written consent.

Participants are given the right to withdraw from participation should they wish to, as well as to opt out of answering questions. Participants have a right to withdraw without explanation. Patients provide permission to collect identifying information to allow follow-up. As soon as follow-up is complete, all identifying information is removed from the dataset so the data becomes de-identified and the participant is allocated a study ID.

Data Collection

Following consent the patient participates in face-to-face interviews with the ANP where a structured questionnaire will be completed (there are no qualitative interviews). The questionnaire has been developed by an expert group of geriatricians, and old age psychiatry.

Data collection includes socio-demographic details, MH diagnosis, co-morbidities,

Outcomes:

Sarcopenia: The SARC-F (tool title not an abbreviation) is a screening tool for sarcopenia ((Malmstrom et al 2013). SARC-F comprises five components using self-report on: strength, assistance walking, rise from a chair, climb stairs, and falls. SARC-F scale scores range from 0 to 10 (i.e. 0–2 points for each component; 0 = *best* to 10 = *worst*) and are dichotomized to represent symptomatic (4+) vs. healthy (0–3) status (Malmstrom et al 2016).

Frailty: Clinical Frailty Scale (CSF) is a judgement-based frailty tool that evaluates specific domains including comorbidity, function, and cognition to generate a frailty score ranging from 1 (very fit) to 9 (terminally ill), a higher score indicates poorer physical and cognitive function (Rockwood et al 2005, Church 2020).

The Global Physical Health Scale v1.2 is a four-item validated general health questionnaire Riley et al 2010, Hays et al 2015). Four items are used to assess global physical health. Three items (rate your physical health, everyday activities , rate your fatigue) of these are administered using five-category response scales. Higher scores indicated better health. One item (rating of pain on average) uses a response scale of 0–10 that is recoded to five categories (0 = 1; 1-3 = 2; 4-6 = 3; 7-9 = 4; 10 = 5), the scale is then reverse coded, i.e. 0 (no pain)= 5). Overall scores range from 5 to 20 indicating best possible physical health (PROMIS 2021)

Mental health: Bespoke mental health items. Two items (rate your overall mental health, rate your mood (sense of well-being) over past seven days was rated on a 5 point scale (excellent =5; very poor =1). Items are presented separately, scores range from 1 to 5, higher score indicates better mental health.

Exercise: Two items from Yale Physical Assessment Scale (vigorous exercise frequency and duration over past 7 days, and Walking for exercise frequency and duration over past 7 days ((De Abajo et al., 2001). Frequency was rated on a 4 point scale (not at all=0; 1-2 times=1, 3-4 times=2 or >4 times=3) Duration (0=not applicable, 1=10-30 mins, 2=31-60 mins, 3> 60 mins. Scores are calculated by multiplying Frequency score X Duration score (no weight was applied). Higher scores indicate more activity. Items were not combined for an overall exercise score.

Post intervention, we added an additional question specific to the exercises on the information leaflet

In the past week (7 days) have you completed the exercises on the information leaflet

Frequency (None=0, 1 day=1, 2 days=2; 3 days=3, 4days=4, 5 days=5); X Duration (none =0; 10 mins=1, 11-20 mins=2 , 21-30 mins=3, >30 mins=4). Higher values indicate greater exercise intensity (min score 0 to 20).

Nutrition: Simplified nutritional appetite questionnaire (SNAQ) is a four item scale (rate appetite, When I eat I feel full, food tastes, normally I eat) are rated on a five point scale (1 to 5). Total possible score range from 5 to 20, higher scores indicate better appetite. SNAQ score 14 indicates significant risk of at least 5% weight loss within six months (Kruizenga et al., 2005).

Protein intake: Patients self-reported the number of protein portions eaten in the previous day: Protein was categorised as: meat/fish; milk/diary; eggs/cheese; vegetable protein

The one-month questionnaire focused on acceptability of intervention and ease of use.

Patients are also be asked to give qualitative feedback on the intervention.

The 3-month questionnaire repeated the baseline measures and adherence questions.

Implementation outcomes:

Acceptability (Bespoke item)

One item measures acceptability: The exercise and nutrition advice was acceptable to me (made sense) rated on a 5 point Likert scale (1=strongly disagree to 5 strongly agree)

Ease of Use (Bespoke item)

One item measured Ease of Use ' To what extent was it easy to incorporate the exercise an nutrition advice into your daily routine rated on a five point Likert scale (1=very difficult to 5 very easy)

Recommend to others (bespoke item)

The final item sought participants opinion on 'recommending the intervention to others. 'In your opinion, should we continue to offer this advice and information leaflets to other people attending our service? With three response options Yes/No/ Don't know

A study log is maintained recording the number of eligible patients invited to participate, the number of patients who refused, reasons for refusal, number of patients who consented, number of patients who completed 1-month and 3-month follow-up.

Data management

Data is collected using a paper questionnaire. The data collector is not blinded to the study intervention.

Each participant is allocated a study ID that links the study register maintained by clinical site to the questionnaire data. The patient ID file will be stored separately from the Research data with a Participant ID used to link the two files. The excel sheets are stored in a password protected PC in the HSE in a locked office facility. Paper questionnaires are stored in a locked filling cabinet on the clinical site in the HSE facility

Only de-identified data using a Study ID is shared with UCC PI (CN) using encrypted and password protected file. As soon as the 3-month follow-up is completed (within 6 months of the study start date), the Study Register linking identifiable data with the questionnaire data is destroyed at the clinical site.

Data is analysed using SPSS software V27, the database is stored in a UCC icloud (one drive). Once data is entered and verified, all paper questionnaires and study register are destroyed. Only the study team have access to the data.

Analysis

Data analysis uses descriptive statistics. Categorical data is presented as proportions and percentages, continuous data as medians inter quartile ranges. Non-parametric paired statistics is used to compare the pre and post data, however sample size is too small for a comprehensive analysis.

Patient Safety Protocol

The participants are part of the mental health services, the interviews are undertaken by an experienced cANP, who has worked as a community mental health nurse for > 15 years. If there are signs of patient deterioration, the patients is managed per standard mental health protocols. The ANP discontinues study data collection to focus on the person's clinical management. Based on clinical presentation the person may be referred for urgent review to OPD clinic, or admission to acute MH unit.

Church, S., Rogers, E., Rockwood, K. *et al.* A scoping review of the Clinical Frailty Scale. *BMC Geriatr* **20**, 393 (2020). https://doi.org/10.1186/s12877-020-01801-7

Ida S, Kaneko R, Murata K. SARC-F for Screening of Sarcopenia Among Older Adults: A Meta-analysis of Screening Test Accuracy. J Am Med Dir Assoc. 2018 Aug;19(8):685-689. doi: 10.1016/j.jamda.2018.04.001. Epub 2018 May 31. PMID: 29778639.

Pearson E, Siskind D, Hubbard RE, Gordon EH, Coulson EJ, Warren N. Frailty and severe mental illness: A systematic review and narrative synthesis. J Psychiatr Res. 2022 Mar;147:166-175. doi: 10.1016/j.jpsychires.2022.01.014. Epub 2022 Jan 8. PMID: 35051715.

Malmstrom TK, Morley JE. SARC-F: a simple questionnaire to rapidly diagnose sarcopenia. J Am Med Dir Assoc. 2013 Aug;14(8):531-2. doi: 10.1016/j.jamda.2013.05.018. Epub 2013 Jun 25. PMID: 23810110.

Malmstrom TK, Miller DK, Simonsick EM, Ferrucci L, Morley JE. SARC-F: a symptom score to predict persons with sarcopenia at risk for poor functional outcomes. J Cachexia Sarcopenia Muscle. 2016 Mar;7(1):28-36. doi: 10.1002/jcsm.12048. Epub 2015 Jul 7. PMID: 27066316; PMCID: PMC4799853.

Mutz J, Choudhury U, Zhao J, Dregan A. Frailty in individuals with depression, bipolar disorder and anxiety disorders: longitudinal analyses of all-cause mortality. BMC Med. 2022 Aug 30;20(1):274. doi: 10.1186/s12916-022-02474-2. PMID: 36038880; PMCID: PMC9425946.

Hays RD, Spritzer KL, Thompson WW, Cella D. U.S. General Population Estimate for "Excellent" to "Poor" Self-Rated Health Item. J Gen Intern Med. 2015 Oct;30(10):1511-6. doi: 10.1007/s11606-015-3290-x. Epub 2015 Apr 2. PMID: 25832617; PMCID: PMC4579204.

PROMIS (2021) GLOBAL HEALTH SCORING. MANUALhttps://www.healthmeasures.net/images/PROMIS/manuals/Scoring_Manual_Only/PROMIS_Global_Health_Scoring_Manual.pdf

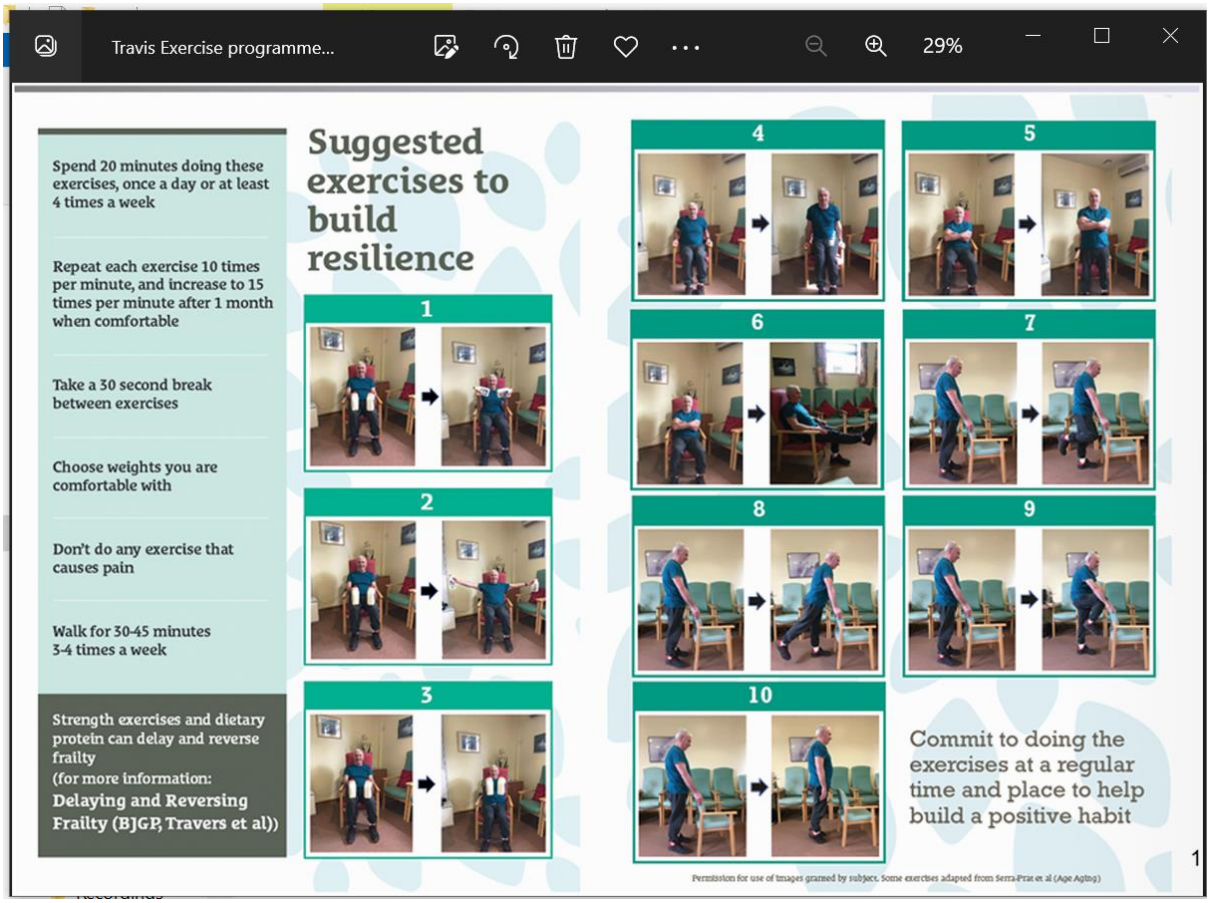
Riley, C D., , W., Stone, A., Rothrock, N., Reeve, B., Yount, S., ... & PROMIS Cooperative Group. (2010). The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005–2008. *Journal of clinical epidemiology*, *63*(11), 1179-1194.

Rockwood K, Song X, MacKnight C, Bergman H, Hogan DB, McDowell I, Mitnitski A. A global clinical measure of fitness and frailty in elderly people. CMAJ. 2005 Aug 30;173(5):489-95. doi: 10.1503/cmaj.050051. PMID: 16129869; PMCID: PMC1188185.

Travers J, Romero-Ortuno R, Cooney MT. Testing the feasibility of a primary-care exercise intervention to prevent and reverse early frailty and build resilience in community-dwelling older adults. EClinicalMedicine. 2022 Mar 22;46:101355. doi: 10.1016/j.eclinm.2022.101355. PMID: 35340628; PMCID: PMC8943408.

Travers J, Romero-Ortuno R, Power D *et al.* Protocol for a randomised controlled trial of a primary care intervention to Reverse Frailty and Enhance Resilience through Exercise and dietary protein Education in community-dwelling adults aged 65 and over [version 2; peer review: 2 approved]. *HRB Open Res* 2021, **3**:91 (https://doi.org/10.12688/hrbopenres.13188.2)

Appendix patient information leaflets



- **PLAN YOUR MEALS** to include good protein sources
- Aim to eat 20g of protein **WITHIN 1 HOUR OF EXERCISING** for best muscle building, with the balance of daily protein at regular intervals throughout the day
- **VARY YOUR DIET** to keep it interesting and to benefit from a variety of proteins
- **ENCOURAGE OTHERS** by eating with your partner, family or friends
- **PLANT-BASED PROTEIN IS BETTER** for our heart and the environment
- **BE MINDFUL OF ALLERGIES** to eggs, dairy, fish, peanuts, shellfish & soy beans

For more information about reversing frailty and building resilience see:
Travers et al, BJGP

My Nutrition Plan For Strength and Resilience

Having enough protein in our diet can help build resilience and avoid frailty. We all lose muscle mass as we age. This can contribute to reduced independence and frailty. Our bodies use protein to strengthen and repair muscles and bones. That's why it's essential to have enough protein in our diet.

- Aim for 1.2 grams of protein per 1 kg of body weight each day e.g. a 70kg adult needs to eat 84 grams of protein each day
- My daily protein target is: body weight (kg) x 1.2 = _____ g

Nutritional Information

Whole Milk
250ml glass of whole milk = 8g protein
Added benefit: Calcium, Vitamin D
Calories: Low
Saturated fat: Low
Cost: Low €

Boiled Egg
1 boiled egg (med) = 6g protein
Added benefit: B12, Vitamin D, Iron, Calcium
Calories: Low
Saturated fat: Low
Cost: Low €

Chicken Breast
160g breast (med) = 35g protein
Added benefit: Iron
Calories: Low
Saturated fat: Medium
Cost: Medium €€

Beef Steak
225g striploin = 44g protein
Added benefit: Iron
Calories: Medium
Saturated fat: High
Cost: High €€€

Salmon Fillet
120g grilled salmon = 30g protein
Added benefit: Omega-3
Calories: Medium
Saturated fat: Low
Cost: High €€€

Cod Fillet
140g baked cod = 25g protein
Added benefit: Omega-3, B Vitamins
Calories: Low
Saturated fat: Low
Cost: High €€€

Tuna Steak
100g can of tuna (in brine) = 27g protein
Added benefit: Iron, Omega-3
Calories: Low
Saturated fat: Low
Cost: Low €

Fish Finger
3 fish fingers = 10g protein
Added benefit: Omega-3, B Vitamins
Calories: Low
Saturated fat: Low
Cost: Low €

Nutritional Information

Chedder Cheese
20g slice cheddar = 5g protein
Added benefit: Calcium, Vitamin D, A, B12, Zinc
Calories: High
Saturated fat: Medium
Cost: Low €

Greek Yogurt
100g yogurt = 18g protein
Added benefit: Vitamin D, B12, Potassium, Calcium
Calories: Medium
Saturated fat: Low
Cost: Medium €€

Almonds
20 whole almonds = 5g protein
Added benefit: Zinc, Magnesium, Good Fats, Fibre
Calories: High
Saturated fat: Low
Cost: Medium €€

Peanut Butter
2 tablespoons peanut butter = 6g protein
Added benefit: Magnesium, Good Fats, Fibre
Calories: High
Saturated fat: Medium
Cost: Low €

Baked Beans
200g Can/snap pot of baked beans = 9.5g protein
Added benefit: Fibre
Calories: Low
Saturated fat: Llow
Cost: Low €

Lentils
100g boiled lentils = 12g protein
Added benefit: Fibre, B Vitamins, Iron, Magnesium, Zinc
Calories: Low
Saturated fat: Low
Cost: Low €

Tofu
100g baked tofu = 16g protein
Added benefit: Iron, Calcium, Magnesium
Calories: Low
Saturated fat: Low
Cost: Low €

Protein Milk
Protein milk drink 250ml = 27g protein
Added benefit: Calcium, Vitamin D, B12
Calories: Low
Saturated fat: Low
Cost: Low €

Feasibility study to test the implementation of health promotion advice (exercise and protein intake) for older people attending a community mental health service.

Participant information leaflet

Principal Investigator Name: Professor Corina Naughton
Principal Investigator Role: Professor of Nursing in Older Person Health Care, University College Cork, Telephone number 021 490 1551

About the project:
This is a research study being undertaken as part of an MSc. Dissertation through the School of Nursing and Midwifery, University College Cork.
As we age, we experience a decrease in muscle strength, energy and ability to undertake some activities (shopping, cooking, or housework). Frailty is a term used to describe this decrease in energy and muscle strength. We know that participating in regular exercise and eating protein (chicken, meat, fish, nuts) can help muscle to stay strong.

What does the study involve?
During your normal routine clinic or home visit, one of your medical team [Aoife Kelly] will provide you with a brief (<10 minutes) health advice on exercise and how to increase protein in your regular diet. You will also receive two information leaflets to take away. While at home, we would like you to carry out the exercises at your own pace and to gradually increase protein in your diet.

We want to see what (if any) effect the advice (on exercise and protein) has on your regular habits and how you feel about your physical and mental health.

we would like to collect some information from you at the start of the project (before the advice), 1 month and 3- months after receiving the advice leaflets. We will collect the information:

1) In a face-to face interview, the researcher (A Kelly) will ask you questions and record the information in a structured paper questionnaire. The questions will be about your health, physical activity, level of exercise and appetite. The interview will take about 10 minutes. There are no right or wrong answers and we would like you to be as frank as possible.
2) We would like your permission to collect information from your medical record about your diagnosis and any other physical health conditions.
3) In one months' time (4 weeks), Aoife will ring you to see how you are doing with the exercise and protein advice and if you have any questions, the phone call will take 5-10 minutes.
4) In three months' time (12 weeks), Aoife, will ring you again and ask similar questions about how you are feeling, your level of physical activity, appetite and if you were able to carry out the exercises. The interview will take about 10 minutes. If you are due back to clinic, we can do the interview with you at the clinic.

Why are we contacting you?
We are inviting all service users aged 65 years and older attending the older adult Mental Health Services in South Lee catchment area Cork Kerry community Healthcare to participate in this study.

Do I have to take part?
No, you do not have to participate in the study. If you decide not to participate, it will have no impact on any aspect of your care in any way. You are also free to change your mind and withdraw from the study at any time during the interview or follow-up.

What will my involvement require?
If you agree to take part, we will ask you to sign a consent form so we can use your data (information) as part of the study. You will not be identified by name in any of the research data. A researcher (Ms. A Kelly) will ask you questions and provide the Health advice and information leaflets during your normal outpatient clinic or home visit. We will fit the research study around your schedule, so there is minimal interruption.

What are the possible disadvantages or risks of taking part?
There is minimal risk associated with the study. If you become tired at any stage during the interview, you can ask the researcher to stop. The exercises have been designed to be as low risk as possible for older people, however with any activity there is a small risk that you could fall or hurt yourself. We ask people to only go at your own pace and to build up the exercise slowly. There is minimal risk in eating recommended amounts of protein as part of a balanced diet, but if you do not regularly eat protein then it is useful to build up slowly.

What are the possible benefits of taking part?
There may be no direct benefit for you in taking part in this study. The study will not change your current treatment plan. You may notice a positive change in the amount of exercise you can do and your fitness. The study will tell us if this type of activity is useful for older people with mental health conditions. We anticipate that this information will help guide treatment and care plans for patients identified as frail or at risk of frailty

Data Protection Notice

We treat your privacy seriously. Any personal data which you provide to the researcher will be treated with the highest standards of security and confidentiality, in accordance with Irish and European Data Protection legislation. This notice sets out details of the information that we collect, how we process it and who we share it with. It also explains your rights under data protection law in relation to our processing of your data.

Who we are

Throughout this notice, ‘’we’’, ‘’us’’, and ‘’our’’ refers to University College Cork, as study sponsor. For more information about us please refer tour website:www.ucc.ie

How we will use your personal data

By participating in the study and performing the study exercises, information from you (also called “personal data”) will be collected for the study purposes mentioned in the Patient information leaflet above. This personal data includes, for example:

- Your name and telephone number so we can contact you at 1 and 3 months follow-up. Once the data collection is finished, we will delete your name and number from the research data, so nobody will be able to identify you from the study.

Your personal data (name and telephone number) will not leave the clinical site, only members of your mental health team will have access to this information.

We will also collect information on your age, gender, health conditions, physical activity and appetite. Personal data collected at any time during the study will be kept strictly confidential. To ensure confidentiality, the data generated during the study is **coded** with a number that will identify you in the study. Any information that leaves the clinical site will be labelled with your code instead of your name. Every person that has access to your uncoded data is subject to professional secrecy and confidentiality. We will not remove any of your uncoded personal data from the clinic e.g. your name or telephone number. During the course of the study, if you disclose information that we feel has implication for your safety or the safety of other people, we will have to relay this information to a member of your mental health team. Before we do this, we will discuss the issue with you.

Who will access my personal data?

Your coded data will only be accessible to the study investigator and study staff. Results of the study will be provided to the Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC) in compliance with national and international regulations on clinical studies.

The purpose and legal basis for collecting your data

Any personal data you provide to us during the course of this study will be processed fairly and lawfully. Signing the Informed Consent Form means that your personal data will be used for the purposes outlined in the Patient information leaflet (PIL).
Personal data collected during this study and the results of the study may be presented for scientific purposes. However, you will never be identified individually during these presentations. Your identity will not be revealed in any reports or publications.

The clinical site and the investigator will use your personal data within the scope defined above.

The General Data Protection Regulation allows us to process your data because you have provided your consent. You are entitled to withdraw your consent at any time.

How long we will keep your data

The personal data (name and telephone number) in the study register will be kept for six months by your clinical team and will not be transferred to any third party. Once the data entry is completed we will delete your name and telephone number from our research data. The remaining research data be stored for 10 years in line with the UCC Code of Research Conduct V2.4 dated 14 SEP 2021. Thereafter, they may be stored for a further period of time for legal reasons (e.g. revised retention obligations), or more if required by law.

Your rights

You have various rights under data protection law, subject to certain exemptions, in connection with our processing of your personal data, including the right:

- to find out if we use your personal data, access your personal data and receive copies of your personal data;
- to have inaccurate/incomplete information corrected and updated;
- in certain circumstances, to have your details deleted from systems that we use to process your personal data or have the use of your personal data restricted in certain ways;
- to object to certain processing of your data by UCC;
- to exercise your right to data portability where applicable (i.e. obtain a copy of your personal data in a commonly used electronic form;
- to withdraw your consent to the processing of your data at any time without giving a reason by notifying your decision to the investigator. This will not affect the lawfulness of processing data about you based on your consent before the withdrawal. If you withdraw your consent for data processing, your participation in the study stops and no further data will be collected from you. Your study physician will present you the options you have concerning your personal data.
- Along with study withdrawal, you have the right to request the deletion of data about you if your data are no longer necessary for the purposes of processing or there is no other legal ground for their further processing.

If you wish to exercise any of these rights, please address your request to the study physician or the Information Compliance Manager, University College Cork (details below).

Questions or Complaints

If you have any queries in relation to this study please contact Professor Corina Naughton (details below). If you have any complaints in connection with our processing of your personal data, you can contact UCC's Information Compliance Manager: **Information Compliance Manager, Office of Corporate & Legal Affairs, University College Cork, Western Road, Cork E: foi@ucc.ie Tel: +353 21 4903949**

You also have the right to lodge a complaint with the Data Protection Commission if you are unhappy with our processing of your personal data. Details of how to lodge a complaint can be found on the Data Protection Commission's website (www.dataprotection.ie), or by telephoning 1890 252 231.

What if there is another concern?
Any complaint or concern about any aspect of the way you have been treated during the course of the study will be addressed; please contact Professor Josephine Hegarty, Head of School of Nursing and Midwifery, University College Cork (J.Hegarty@ucc.ie.ie)
Full contact details of Principal Investigator:
Professor Corina Naughton,
Professor of Nursing in Older Person Health Care, University College Cork
Telephone number 021 490 1551 corina.naughton@ucc.ie
Who has reviewed the project?

This study was submitted to Cork Research Ethics Committee (CREC).

Thank you for taking the time to read this Information Sheet.

Feasibility study to test the implementation of health promotion advice (exercise and protein intake) for older people attending a community mental health service

Consent Form for Participants

Principal Investigator: Professor Corina Naughton, Professor of Nursing in Older Person Health Care, University College Cork, School of Nursing and Midwifery, Brookfield Campus, Cork. Email: corina.naughton@ucc.ie

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet, please ask the researcher before you decide whether to join in.

I confirm that I understand that by ticking/initialling each box I am consenting to this element of the study. I understand that it will be assumed that unticked/initialled boxes mean that I DO NOT consent to that part of the study. I understand that by not giving consent for any one element I may be deemed ineligible for the study. ☐

1. **I confirm that I have read and understood the information sheet dated [v1 .2] for the above study. I have had the opportunity to consider the information and asked questions which have been answered satisfactorily.** ☐
2. **I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.** ☐
3. **I understand that information will be handled in accordance with the terms of the Data Protection Act 2018 and as outlined in the Data Protection Notice in the Patient Information Leaflet.** ☐
4. **I understand that my information may be subject to review by responsible individuals from the ethics committee or UCC for monitoring and audit purposes.** ☐
5. **I understand that confidentiality and anonymity will be maintained and it will not be possible to identify me in any publications. However, I understand that in the event of significant risk to myself or others confidentiality may have to be breached** ☐
6. I agree that the research team may store and use my de-identified data for future research for up to ten years. Data would not be identifiable in any report. ☐
7. I understand that the information I have submitted will be published as a report and in academic journal. ☐

8. I understand that I must not take part if I fall under the exclusion criteria as detailed in the information sheet and explained to me by the researcher. ☐

9. I have informed the researcher of any other research in which I am currently involved or have been involved in during the past 12 months ☐

STORAGE AND FUTURE USE OF INFORMATION		
I give permission for material/data to be stored for possible future research related to the current study with my future consent and only if the research is approved by a Research Ethics committee	Yes ☐	No ☐

Name of Participant	**Date**	**Signature**
Name of Researcher		