FULL STUDY TITLE

CanaCare: **Person-centred care planning in an interdisciplinary team**

SHORT STUDY TITLE

CanaCare

CONFIDENTIAL

STATEMENT OF COMPLIANCE FOR NON DRUG OR DEVICE CLINICAL TRIALS

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (as updated) and the Handbook for Good Clinical Research Practice (GCP). The Therapeutic Goods Act has adopted ICH Guideline for Good Clinical Practice.

Contents

1. GENERAL INFORMATION

Study Protocol: CanaCareTrial, 29th July 2020.

Partly funded by Seed Funding Scheme: Mental Health, Drug and Alcohol Comorbidity.
Study Sponsor: University of Sydney.

CHIEF INVESTIGATOR:

CI Professor Maria Fiatarone Singh
University of Sydney,
Susan Wakil Building D18
CamperDown, NSW.
Telephone: 02 9351 9755
Email: maria.fiataronesingh@sydney.edu.au
Role: Chief investigator (CI), Study physician
Responsibilities: Oversight of the study, development of screening, intervention and assessment protocols, responsible for data integrity and management, study physician, responsible for confirming participant's eligibility into the study, gathering of medical history, current symptoms and health concerns, and conducting physical examination, primary contact for participants who experience an adverse event, assessment of maximal aerobic capacity during exercise stress testing, data analysis and interpretation, preparation of manuscripts.

ASSOCIATE INVESTIGATORS:

University of Sydney

Dr Yorgi Mavros
University of Sydney,
Susan Wakil Building D18
Camperdown, NSW.
Telephone: 029351 9279
Email: yorgi.mavros@sydney.edu.au
Role: Associate investigator, Accredited exercise physiologist
Responsibilities: Associate investigator and study budgetary manager, development of analysis and reliability protocols, development of intervention and assessment protocols, assistance in the development of manual of procedures, ethics and trial governance documentation, oversight of DXA assessments data analysis and interpretation, preparations of manuscripts.

Ms Hulya Sinmaz
University of Sydney,
Susan Wakil Building D18
Camperdown NSW.
Email: hulya.sinmaz@sydney.edu.au
Role: Phd student, Accredited exercise physiologist
Responsibilities: HDR student, preparation of ethics application and trial governance documentation, maintenance of trial documentation and database, reporting of adverse events, serious adverse events and suspected unexpected serious adverse reactions to the Ethics Committee (in accordance with HREC requirements), development of manual of procedures, assistance in the development of screening, intervention and assessment protocols, recruitment and screening of participants, delivery of the exercise interventions, data analysis and interpretation, preparation of manuscripts.

Mr Kenneth Daniel
University of Sydney,
Susan Wakil Building D18
Camperdown, NSW.Telephone: +61 433 899 305
Email: kenneth.daniel@sydney.edu.au
Role: Associate investigator, Accredited practising dietician
Responsibilities: Assessment of dietary intake, body composition and nutritional status, development of nutritional plan relevant to participant goals and health issues identified, data analysis and interpretation, preparation of manuscripts.

Mrs Carolina Almendrales Rangel
University of Sydney,
Susan Wakil Building D18
Camperdown, NSW.
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Role: Associate investigator, Accredited practising dietician
Responsibilities: Assessment of dietary intake, body composition and nutritional status, development of nutritional plan relevant to participant goals and health issues identified, data analysis and interpretation, preparation of manuscripts.

Mr Guy Wilson
University of Sydney,
Susan Wakil Building D18
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Role: Associate investigator, Accredited exercise physiologist
Responsibilities: Assessment of exercise capacity and physical performance, development and delivery of the physical activity prescription or exercise plan as appropriate,

assessment of mental health and wellbeing, data analysis and interpretation, preparation of manuscripts.

Mrs Yareni Guerrero
University of Sydney,
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Role: Associate investigator, Accredited exercise physiologist
Responsibilities: Assessment of exercise capacity and physical performance, development and delivery of the physical activity prescription or exercise plan as appropriate, assessment of mental health and wellbeing, data analysis and interpretation, preparation of manuscripts.

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Dr Kerry Peek
University of Sydney,
Susan Wakil Building D18
Camperdown, NSW.
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Role: Associate investigator, Accredited physiotherapist.
Responsibilities: Conduct musculoskeletal assessments/diagnosis, development of treatment and intervention planning, data analysis and interpretation, preparation of manuscripts.

Dr Jeffrey Rogers
University of Sydney,
Susan Wakil Building D18
Camperdown, NSW.
Telephone: +61 2 9351 9261
Email: Jeffrey.rogers@sydney.edu.au
Role: Associate investigator, Registered Psychologist
Responsibilities: Performing psychological and cognitive assessments; providing, developing and implementing psychological and psychosocial interventions, supporting participants who present with: feelings of depression, anger, or anxiety, social isolation, managing a chronic health condition, coping strategies to use in stressful situations, insomnia or fatigue, substance-use disorders, reintegration into family or social relationships; data analysis and interpretation, preparation of manuscripts.

University of New South Wales

Dr Belinda Parmenter
University of New South Wales
Faculty of Medicine
Telephone: 02 9385 8313
Email: b.parmenter@unsw.edu.au
Role: Associate investigator, Accredited Exercise Physiologist

Responsibilities: Development of protocols, data analysis and interpretation, preparation of manuscripts.

Cana Communities: Cana Farms

Julie Sneddon
Cana Communities
Po Box 1651
Strawberry Hills NSW 2012
Tel: 0414 649153
E: juliesneddon@live.com
Responsibilities: Liaison with Cana Communities clients and staff, oversight of protocols for advertising the CanaCare program to Cana clients, development of social support and social engagement protocols, assistance with logistics of transportation to the clinic at Camperdown and accessing Zoom, assistance with data interpretation and preparation of manuscripts, dissemination of results to Cana Community and others.

Cana Communities Affiliated Nurse
Mater Hospital Sydney
50 Rocklands Rd,
North Sydney NSW 2060
Tel: 9923 2777
Responsibilities: Assistance with monitoring adherence and engagement with the components of the CanaCare wellness program as regards to exercise and nutritional behaviours and medication usage, liaison with general practitioners and other health care practitioners in the community as needed, assistance with data interpretation and preparation of manuscripts.

Community Health Professionals

Mevsim Sinmaz
Australian Disability Services
Auburn NSW 2144
Telephone: +61 402 581 731
Email: mevsimsinmaz@gmail.com
Role: Associate investigator, Registered Psychologist
Responsibilities: Performing psychological and cognitive assessments; providing, developing and implementing psychological and psychosocial interventions, supporting participants who present with: feelings of depression, anger, or anxiety, social isolation, managing a chronic health condition, coping strategies to use in stressful situations, insomnia or fatigue, substance-use disorders, reintegration into family or social relationships; data analysis and interpretation, preparation of manuscripts.

Mrs Ketki Prabhu Ahuja
Berowra Heights
Telephone: +91 9881440205
Email: kahu8123@uni.sydney.edu.au
Role: Associate investigator, Accredited Exercise Physiologist
Responsibilities: Assessment of exercise capacity and physical performance, development and delivery of the physical activity prescription or exercise plan as appropriate, assessment of mental health and wellbeing, data analysis and interpretation, preparation of manuscripts.

2. SYNOPSIS

CanaCare is an interdisciplinary clinic and translational research study focused on health and wellness promotion for individuals who have experienced mental and physical health challenges due to a variety of circumstances, and are seeking assistance with lifestyle advice and choices which may lead to improved wellbeing, social integration, and engagement in their communities. The CanaCare team consists of a physician, accredited practising dietitians, accredited exercise physiologists, registered physiotherapists, registered psychologists, social workers, and a pharmacist. The clinic will utilise a person-centred approach for the delivery of a holistic assessment of each individuals physical and psychological health status and goals. The clinic team and the client will together structure a plan for reaching these goals which may include structured exercise (Linke et al, 2015; Hallgren et al, 2017, Lynch et al, 2013), nutritional changes (Opie et al, 2015; Teasdale et al, 2017), medication review, psychological support and counselling, control of substance use, referral to other health care practitioners for ongoing care or specialised tests, as well as behavioural support and ongoing feedback. Participants will be those individuals who have engaged with the Cana Communities not-for-profit organisation in any of its ongoing programs in NSW. The organisation supports individuals who have a wide variety of mental health conditions, disabilities, substance-use disorders, have been recently released from incarceration, those who have experienced loneliness and social isolation or disengagement, homelessness, domestic violence, refugees and those who have experienced trauma in its many forms.

Our primary outcome will be Happiness measured using the Oxford Happiness Scale, measured at baseline and 6 months. Secondary outcomes will include depressive symptoms, anxiety, sleep, quality of life, physical activity levels, dietary intake, body composition, exercise capacity, and functional mobility, as well as social integration/stability in domains of work, education, residential status, and relationships. (If there is no specific

scale, we will just ask the question about these areas before and after, to determine job status, living situation, etc).

3. RATIONALE / BACKGROUND

"But equal treatment in an unequal society could still foster inequality".

Mathew Desmond (2016)

"[Patient centred care] M*edicine of the person, for the person, by the person, and with the person".*

International College of Person-Centered Medicine (2019)

Cana Communities is a registered not-for-profit charity that was first established in 1975. The focus of the organisation is in helping people who are most in need, those who may have a mental health condition, substance-use disorders, are experiencing homelessness, are suffering from loneliness, and other factors which alienate them from society (Cana Communities, 2017). The organisation offers society's most marginalised people support as they slowly reintegrate, and transition into stable living. This is achieved through social support provided by staff and volunteers, supported housing, employment, and educational opportunities.

Across Australia there are numerous outreach programs provided by Cana Communities. To name a few, the De Porres House in Darlinghurst, established in 1975, provides transitional and permanent accommodation for men and women. Referrals can be made for individuals who have been released from correctional facilities, are homeless, and asylum seekers without financial government support. The Nagle House in Redfern is a residential home, established in 2012 with 10 single rooms; that provides a safe, transitional home for women who have experienced trauma. Since 2012, Cana Farm, situated on the outskirts of Sydney, has been offering much more than organic vegetables to their community. The farm employs 14 people in transitional employment, providing more flexibility than a regular workplace, which is vital for this cohort to succeed. The prison release support program at Cana Farm offers men at the *Compulsory Drug Treatment Correctional Centre* employment within the community, to assist in effective re-integration within society (Taguchi, 2017). The individuals that Cana Communities seeks to support are those who have experienced serious mental

and physical challenges in their life. Thus, by developing better life skills, their overall health and mental health have improved. There is a need to provide further support avenues for these individuals to improve their overall health and wellbeing. Health is defined as inclusive of physical, mental, and social well-being, and not purely the absence of disease (WHO, 2014). Aptly titled, *"All is not equal",* the Australian Institute of Health and Welfare (AIHW) highlight the important role of social determinates of health in Australia (2018). There are significant disparities in the health outcomes of people living in poorer socioeconomic conditions. Disadvantaged Australians experience greater levels of disease risk factors and lower use of preventative health services, compared to those with a socioeconomic advantage (Australian Bureau of Statistics [ABS], 2010). There are other factors that can contribute to disadvantage that extend beyond financial factors, such as poor health, disability, low education, social support, limited community participation, low health literacy, and social exclusion, among others (AIWH, 2017). Statistically, 11.5 percent of Australians over the age of 15 years, experienced deep and persistent disadvantage due to unemployment, 11.2 percent with a long-term health condition or disability, and 15.3 percent of individuals dependent on income support. It has been shown that 62.1% of people aged 15-64 years with a mental or behavioural condition were employed, compared to 79.5% without a mental or behavioural condition (ABS, 2010). The World Health Organization (WHO) stipulates that social inequalities and disadvantage are the primary reason for unfair and avoidable differences in health status and longevity across groups within society (2008).

The aim of CanaCare is to offer support for individuals who have experienced disadvantage, and have sought engagement with the Cana Communities organisation. The Clinic will be available to all those who are seeking assistance with lifestyle advice and life choices which may lead to improved wellbeing, social integration, and engagement in their communities. The interdisciplinary clinic includes a physician, accredited practising dieticians, accredited exercise physiologists, registered psychologists, registered physiotherapists, social workers, and a pharmacist. All services and discussions will be conducted to align with the principles of person-centred care; to provide choice, responsibility and autonomy in important health matters that pertain to the individual. Mental health is defined as a state of well-being in which all people realise their potential, cope with daily stressors of life, work productively and fruitfully, and with the ability to contribute to their community (WHO, 2014). It is the aim of the CanaCare clinic to strive to achieve this definition of mental health for participants. The primary outcome in this study is Happiness (Ryan et al, 2001). This focus on happiness is intentionally broader than the lack of depression or negative affect, which traditionally have been the targets of mental health programs. Here, we take a much broader view of the goals of the clinic which are to assist with the integration of identified needs in the areas of mental, physical, emotional, and social aspects of wellbeing. Collectively, we anticipate that these factors will contribute to an improved sense of optimism, positive affect, life satisfaction, and purpose in life, all components of this construct of Happiness.

4. AIMS / OBJECTIVES / HYPOTHESES

The primary aim of the CanaCare program is to utilise a person-centred approach to care planning and delivery, provided in collaboration with an interdisciplinary team with the overall aim of improving the health and wellness for all participants.

Primary Hypotheses

Participation in the interdisciplinary CanaCare program, utilising a person-centred approach, will result in a significant improvement in the Oxford Happiness Score after 6 months.

Secondary aims of the study will be to assess the effect of the study on improvements in nutrition and health status, functional status, sleep quality, physical activity participation, neuropsychological outcomes (including depression, anxiety, self-esteem, and empathy), maximal aerobic capacity, muscle strength, physical performance, anthropometric parameters and body composition (including fat mass, fat free mass and bone mineral density).

5. PARTICIPATING SITES

The study will be conducted, inclusive of screening, enrolment, assessment and intervention delivery, in-person at one or more sites listed below or via a secure online platform such as Zoom . The University of Sydney has software licenses to all 3 platforms. Recruitment will be conducted at Cana Farm and other facilities which are part of Cana Communities in the greater Sydney area via in-person, online or telephone. Screening and medical assessments will be conducted privately at the University of Sydney or via a secure online platform with additional contact by telephone or email as needed.

Site 1:
University of Sydney, Camperdown Campus
Susan Wakil Building.
Camperdown NSW
This site will be used for assessment and delivery of the multi-component interventions and behavioural and psychological support.

Site 2:
Cana Farm
100 Kingswood Road,
Orchard Hills, NSW 2748
This site will be used for the delivery of the exercise and nutritional education interventions, as well as behavioural and psychological support. Exercise training sessions will be offered at this site using the gym equipment, under the direct and remote supervision of the CanaCare team.

Site 3:
De Porres House
114 Flinders Street,
Darlinghurst NSW 2010

This site will be used for the delivery of the exercise and nutritional education interventions, as well as behavioural and psychological support. Exercise training sessions will be offered at this site using the gym equipment (resistance bands, handheld weights, portable equipment etc.), under the direct and remote supervision of the CanaCare team.

Site 4:
Nagle House
371 Cleveland Street,
Redfern NSW 2016
This site will be used for the delivery of the exercise and nutritional education interventions, as well as behavioural and psychological support. Exercise training sessions will be offered at this site using the gym equipment (resistance bands, handheld weights, portable equipment etc.), under the direct and remote supervision of the CanaCare team.

Site 5:
The Garden Shelter
Uniting Church 56a Raglan Street,
Waterloo NSW 2017
This site will be used for the delivery of the exercise and nutritional education interventions, as well as behavioural and psychological support. Exercise training sessions will be offered at this site using the gym equipment (resistance bands, handheld weights, portable equipment etc.), under the direct and remote supervision of the CanaCare team.

6. RESEARCH PLAN / STUDY DESIGN

6.1. TYPE OF STUDY

6-month translational study.

6.2 POPULATION / SAMPLE SIZE INCLUDING POWER CALCULATION

We will recruit men and women who have had any interaction with Cana Communities. This may be via provision of services, general inquiries or individuals who have been identified as suitable for the CanaCare Clinic study by Cana Communities staff and volunteers.

Our sample size calculation is based on a pilot randomised controlled trial in a non-clinical adult population, who were randomly allocated to one of two positive psychology interventions. Effect size and sample size estimates based on the changes in the Oxford Happiness Questionnaire following each intervention are summarised below.

Intervention	Pre (mean)	Post (mean)	Mean difference	Baseline SD	Hedges g	Sample Size
Happiness	3.81	4.14	0.33	0.84	0.38	57
Gratitude	3.83	4.34	0.51	0.67	0.75	16

Sample size estimates were based on within-group changes in the Oxford Happiness Questionnaire, with a critical alpha of 0.05, and a power of 0.8, using a two-tailed t-test. Based on the data above, we would require 57 participants to detect a significant change in the Oxford Happiness Questionnaire. As we are recruiting a marginalised population, it is possible that the effect size following the intervention will be larger, and therefore we believe this reflects a conservative sample size estimate.

6.3 STUDY DESIGN

Participants will be accompanied by a support person from the Cana Communities volunteer pool to the University of Sydney study site or will be supported by their support person to access one of the three online platforms (mentioned above) at a designated time. The participants will initially meet/talk to Professor Maria Fiatarone Singh [study physician] to identify their primary goals/reasons for wanting to take part in the research program. Depending on what the participants identify as their primary (life) goal or aspiration/s, the physical and medical history assessment will focus on areas relevant to their goals.

Participants will then meet with one or more allied health practitioners for additional assessments to be completed. The interdisciplinary team will consist of accredited dietitians, accredited exercise physiologists, social workers, registered psychologists, registered physiotherapists and pharmacists. These assessments may include questionnaires, structured interviews, counselling sessions, body composition testing, nutritional assessments, fitness assessments and drug reviews.

A case conference will be held with all health practitioners involved in the participants' care. Subsequently, a case conference will be held with the team and the participants, with their support person present, to discuss their assessments, and how they relate to their goals. Through discussions with the participant, initial components of the Wellness program will be made. This may include exercise, dietary changes, mental health strategies such as mindfulness or meditation or cognitive behavioural therapy, or lessening of substance use, as appropriate. The care provided by CanaCare will be in addition to the usual supports provided by Cana Communities for effective reintegration into work, housing support, and social relationship building, among other offerings.

The Wellness program may take place across different sites including the University of Sydney Camperdown campus, Cana Communities sites around Sydney and Cana Farm in Orchard Hills and via the secure online platform chosen Programs may be supervised or unsupervised, as appropriate, and will be interdisciplinary in nature. Where relevant, the study physician may make referrals to the participant's general practitioner, a psychiatrist or specialist.

Each participant will be linked with a Cana Communities volunteer from the community who will be his/her primary coordinator of care, depending on the most important or urgent goal or wellness need identified. This person will be responsible for follow-up by telephone on a weekly basis initially, to assist with the adoption of the Wellness program elements.

Follow-up will be planned for 3 months and 6 months to re-evaluate and re-set goals (either in-person or online). The participant will be accompanied/supported by their Cana support person if needed.

6.4 STATISTICAL ANALYSES

Descriptive data on participant characteristics and all outcomes will be generated using parametric and non-parametric summary statistics as appropriate to the distribution of the data. Relationships between variables of interest will be analysed via simple and multiple regression models or Spearman's correlation analyses as appropriate. Outcomes over time will be analysed through ANCOVA repeated measures with main effect of time and additional covariates as identified by review of the baseline data. Effect sizes will be generated for major primary and secondary outcomes of interest. Adherence to programmatic elements will be calculated and all adverse events, related and unrelated to study protocols will be tabulated. A p value of less than 0.05 will be accepted as a threshold of statistical significance. Clinical relevance of any changes observed in health status or behaviours will be determined by comparison to existing data on clinically meaningful changes in the relevant outcomes.

6.5 RECRUITMENT AND SELECTION OF PARTICIPANTS

The study will be advertised through the distribution of flyers from Cana Farm and Cana Communities personnel and through the Cana Communities monthly newsletter. Posters will also be placed across Cana Communities sites across New South Wales. Permission will be obtained from each of these sites prior to advertising the study.

All advertising material will have the contact number and email address of our research team included, and interested participants will contact us directly if they wish to hear more about the study. Alternatively, interested participants can speak to staff at Cana Communities sites and Cana Farm directly for more information about the study, as well as provide verbal consent for staff to provide the research staff with their contact details.

We will avoid real or perceived coercion by indicating in the recruitment flyers and posters that the study is completely voluntary. The Participant Information Sheet will outline that participants can withdraw from the study at any time, and that this will not influence their relationship with Cana Communities, Cana Farm, their own health care providers or health care services in the community, the University of Sydney or the University of New South Wales.

6.5.1 INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria:
We will recruit individuals aged 18 years and over who express interest in the CanaCare study.

Exclusionary criteria:
Participants who present with active suicidal ideation, active psychosis, delirium, acute withdrawal or unstable cardiovascular or other disease will be referred for appropriate treatment, and may be eligible to enrol in the study upon completion of appropriate treatment.

Participants will be excluded if they have a rapidly progressive or terminal illness.

6.5.2 INTERVENTIONS
Below is a description of person-centred care and of each health professional's scope of practice and role within the CanaCare study.

Person-centred care (PCC):
Traditional models of care (TMC) have often been described as deficit or illness-based models, where primacy is given to the illness, symptom or impairment. The overarching emphasis is on curing or managing the conditions, and the individual often plays a passive role in planning. TMC within the mental health sector, has predominantly seen participation in one's community and personal choice often as the 'reward' to compliance with treatment, and symptom reductions.

Person-centred care differs in that it provides participants with the choice of the services they use, and encourages an active or self-directed role. Participants are included in the clinical team, and have discretion to invite family members and other support persons to be involved.

Physician:
The study director/study physician will have overall responsibility for the medical assessment and health and wellness programming offered to each participant. She will undertake a medical history and physical examination at the first assessment when the participant comes to the CanaCare clinic at the University of Sydney or a thorough medical history via a secure online platform. If the latter is performed, a physical examination will be conducted at a later date that is mutually agreed upon and complies with the Department of Health COVID-19 recommendations. Based on this assessment and the person's goals, she will recommend additional assessments which will be performed by the clinic staff. Subsequently, after a case conference is held to review all results, specific elements of the wellness program will be prescribed to be implemented by the clinic staff in collaboration with the participant. These may include nutritional, exercise, and other behavioural strategies to be carried out under supervision or independently, as deemed appropriate and most feasible for each individual. She will not take over the chronic medical care of the participant, but with permission may communicate findings from the assessments to the GP/primary community health care team for ongoing treatment of identified medical conditions or need for further testing. The physician will also have responsibility for adjudicating all adverse events as related to the study or not, and reporting of these adverse events to other health care professionals and the HREC as required.

Dietetics:
Accredited practising dietitians (APDs) have undergone tertiary level training to provide expert nutrition and dietary advice to both individuals and groups on nutritional related matters (Dietitians Association of Australia [DAA], 2015). APDs within the CanaCare team will conduct assessments, perform diagnoses, implement interventions, as well as monitor and evaluate the therapeutic plan (DAA, 2018). They may provide education around healthy eating, shopping, and cooking, weight loss/weight gain, health with the management of a chronic health condition/s related to dietary patterns, and safe use of alcohol.

When working with individuals who have a mental health condition, APDs will utilise client-centred strategies for long-term dietetic and life-style self-management of relevant physical health outcomes, including goals related to long-term medication use (DAA, 2018).

Exercise Physiology:
Accredited exercise physiologists (AEPs) have tertiary level training with the knowledge and skills to design, deliver and evaluate safe and effective exercise interventions for individuals who may have acute, sub-acute or chronic medical conditions, injuries or disabilities (Exercise & Sport Science Australia [ESSA], 2018). The overall aim of the AEP is to prevent, manage and assist individuals to regaining their optimal physical function, health or wellness (ESSA, 2018). If participants elect to see an AEP or exercise scientist, they will design an exercise intervention to improve strength and/or fitness, improve balance and reduce the risk of falls, improve body composition (decreasing fat mass and increasing muscle mass and increasing bone density), and better manage any chronic health condition/s they may have.

Psychology:
Psychology is defined as the study of behaviour and mind (American Psychological Association, 2019d). A psychologists' role is to understand the behaviour of an individual, and are trained to understand how the mind works. Individuals have multiple complexities and factors such as personality, developmental milestones, societal and cultural factors need to be taken into consideration. The psychologist's role is to take in and understand these complexities of a person to provide assessment and intervention according to the individual. The psychologists on the CanaCare team will assist individuals who may have been feeling depressed, angry, anxious, social isolation, fatigue or insomnia. Those who require support for managing a chronic health condition, coping strategies to use in stressful situations, overcoming substance-use disorders, or re-integration into family and social relationships.

Social Work:
Social work is committed to human rights and social justice and the relationship of these issues to health care and wellbeing. Social workers can support individuals, families, groups and communities within the contact of their social, physical and cultural environment, acknowledging their current and previous experiences, as well as their cultural and belief systems (Australian Association of Social Workers, 2019). The social worker on the CanaCare team will assist individuals on many of the issues listed above in psychology, as well as assisting in finding suitable accommodation, employment and educational opportunities.

Pharmacy:
A pharmacist can provide education, counselling around medications and conditions, as well as perform a medication review to optimise the benefits/side effects/drug interactions related to the participant's medication regime in collaboration with a physician. The pharmacist

within the CanaCare team will support participants by reviewing medication regimes with the participant and study physician, assist with adherence of prescribed medications, and provide education about medications and of drug-drug and drug-nutrient interactions and how they affect the health status of the participant.

Physiotherapy:
A registered physiotherapist has completed tertiary level training to assess, diagnose and treat/manage individuals with pain and problems with movement caused by joint, muscles and nerve disorders. Physiotherapists on the CanaCare team will assess the participant, consider their values, take note of their history (medial, psychological, social and cultural aspects) and will conduct an appropriate physical examination - where relevant - to design a suitable treatment plan. This may include providing treatment, advice, prescribing an exercise/mobility/balance program and liaising with other health practitioners, such as exercises physiologists to optimise exercise prescription.

7. ETHICAL CONSIDERATIONS

7.1 ETHICS APPROVAL
Ethics approval will be sought from the University of Sydney Human Research Ethics Committee only.

7.2 INFORMED CONSENT PROCESS
During each stage of the screening process, participants will be informed of the purpose of the screening, and what will happen to their data.

Participants will be provided with a Participant Information Statement (PIS), outlining all the procedures of the study, and what their participation will involve. The PIS will outline any potential risks, and benefits of the study. Participants will be made aware that participation is voluntary, and that they are free to withdraw at any time, without any effect on their relationship with Cana Communities, Cana Farm, the University of Sydney, the University of New South Wales or any investigators in the study.

A research assistant will read the PIS with the participant and with their Cana Support Person present They will provide participants with the opportunity to ask questions, and discuss the study in greater detail. Participants will consent to the study by signing the Participant Consent Form. The Cana Support Person will sign as the witness to the signature.

7.3 CONFIDENTIALITY AND PRIVACY

Data will be collected both in person and over the phone or by videoconferencing (University Zoom account) as needed at various times during the study. The data will be entered into the secure REDCAP database and Prof. Fiatarone Singh's secure USYD data server. Whenever a Zoom meeting is used a password will be sent to the participant/s and meeting details only available to research personnel and the participant/s being interviewed. If a Zoom meeting needs to be recorded so that the data can be extracted later or shared with another research personnel, the resulting file containing the information will be saved to an encrypted local drive (ie., a laptop or a desktop drive, not a removable media such as a USB or removable hard drive). Any such recording with be removed to Prof. Fiatarone Singh's RDS as soon as possible and deleted from the local drive. Data gathered from the physician screening, case conference, assessments, intervention, planning and delivery will be entered by the research

staff into a database created in REDCAP and will also be stored in a secure, University of Sydney server and will be password protected. Data will be entered using a re-identifiable form using unique identity numbers. The code will be used on all electronic data forms, electronic databases and hard copy forms. No forms will contain the names of the participants, or other identifying information. Data gathered from the physician screening, case conferences, assessments, intervention planning and delivery will be entered by the research staff into a database created in REDCAP and will also be stored on a secure, University of Sydney server, and will be password protected. Data will be entered in a re-identifiable form using unique identity numbers. This code will be used on all electronic data forms, electronic databases and hard copy data forms. No forms will contain the names of participants, or other identifying information.

All participant information will remain re-identifiable, so that information that is relevant to their medical care can be communicated to appropriate medical professionals. Participants will only remain re-identifiable to persons directly involved with the study, namely the Primary and Associate Investigators, and Research Assistants or HDR students who are conducting the intervention/assessments.

All data will be de-identified prior to depositing in a repository at the end of the study, as required by the National Health and Medical Research Council.

8. SAFETY CONSIDERATIONS

8.1 ADVERSE EVENTS

Adverse events will be monitored through the administration of a weekly questionnaire and reporting of events throughout the study period. If participants report any adverse events, these will be reported to the University of Sydney HREC. These will be reported even if they may be unrelated to the intervention, this will be adjudicated by the study physician.

Serious adverse events resulting in hospitalisation or death will be reported to the University of Sydney HREC within 24 hours, whether or not they may be unrelated to the intervention. In both cases, participants will be followed-up by phone or in-person until resolution of the adverse event.

8.2 RISKS OF THE STUDY

Outlined below are possible risks associated with different assessments and interventions.

Self-reported/practitioner-administered questionnaires:

Fatigue and psychological distress may accompany testing. This will be minimised by frequent breaks as needed, and highly experienced allied health professionals and research staff conducting the testing. Questionnaires will be performed confidentially in a private area with the participant, Cana Support person and researcher/practitioner present.

Muscle soreness and injury:

As with any exercise testing or training, there are possible risks of injury or a heart attack. Participants will undergo a physician screen prior to any testing procedures being conducted, and medical information will be sought after from the participants GP and/or specialists when necessary to ensure there is no contraindication to exercise testing or training.

The exercise testing may cause some muscle soreness and fatigue. There is also a small risk of musculoskeletal soreness or injury during physical function tests, however, this is very rare during the kind of strength, balance, functional mobility and gait testing proposed here. Participants will be closely supervised by a trained and experienced health professional during all testing procedures. To minimise these risks, we will carefully monitor participants throughout the testing to maximise their safety. Adverse advents during testing will be immediately reported to the study physician, who will take care of those participants suffering from harm related to participation in the study.

To reduce the chance of adverse events during the exercise sessions, each session will start with asking participants how they feel and if there has been any changes to their medical health. Participants will be asked to complete a weekly health check report in which they should indicate if there has been: no special events, worsening of disease, newly diagnosed disease, or if they have been in the hospital. In addition, participants will be asked to classify the cause of the event to different diseases/incidents.

Exercise sessions will be supervised, either directly or remotely, by an experienced health professional. Supervised sessions can be performed in a one-to-one session or in small groups to allow close supervision of each participant. Exercise intensity will be monitored throughout all training sessions via continuous monitoring of rate of perceived exertion, heart rate (aerobic exercise) and close monitoring of signs and symptoms. The exercise session will be terminated prematurely if a participant shows signs of any discomfort. Any events/episode during the exercise session will be followed-up by the study physician.

Radiation:

This research study may involve exposure to a very low amount of radiation from dual X-ray absorptiometry (DXA) scanning for body composition assessment when this is indicated for particular participants. The effective dose of radiation from this study is very low at about 0.06 millisieverts (mSv) over the 12-month period. For comparison, everyone receives a dose of about 2 mSv each year from natural sources as part of everyday living, so the study is equivalent to a few days of natural “background‟ radiation. No harmful effects have been demonstrated at this level and the risk is minimal. Participants are advised to inform the researchers if they have participated in any research study in the last five years where they were exposed to radiation. Participants are also advised to show the participant information statement to the research staff if any other studies they choose to volunteer for in the next 5 years.

Adverse Effects:

During each test procedure, and at regular intervals throughout the program, we will ask participants to inform us of any side effects that they may experience. Participants will be

advised that they must contact the study staff immediately if there are any unusual health experiences, injury or bad effects. This notification should take place whether or not they believe that the problem is related to the program or from some other cause. Prior to any testing, the study physician will review participant's medical history to make sure they are medically ready for the study procedures.

In the event of an injury or other misadventure, we will contact the participant's GP, and may recommend an appropriate course of action in consultation with the GP as necessary. In the event of any adverse effect participants will be able to contact the study physician Professor Maria Fiatarone Singh on 02 9351 9755.

9. OUTCOMES

Table 1 illustrates the CanaCare Clinic primary and secondary outcomes. All participants will complete the Oxford Happiness Questionnaire. Other outcome measures will be completed if they are relevant to the participant's goals.

Table 1. CanaCare Primary and Secondary Outcomes.

Primary Outcomes
1. Oxford Happiness Questionnaire score
Secondary Outcomes
1. Neuropsychological Outcomes 1.1. **Self-efficacy** 1.1.1. Ewart's Self Efficacy Scale 1.2. **Empathy** 1.2.1. Toronto Empathy Scale 1.3. **Quality of Life** 1.3.1. Short Form 36 Health Survey Questionnaire (SF-36) 1.4. **Depression** 1.4.1. Patient Health Questionnaire-9 (PHQ-9) 1.4.2. Hamilton Depression Rating Scale (HAM-D) 1.5. **Anxiety** 1.5.1. Generalised Anxiety Disorder 7-Item (GAD-7) 1.6. **Post-traumatic Stress Disorder Symptoms** 1.6.1. Post-traumatic Stress Disorder Symptom Scale – Interview for DSM-5 (PSS-I-5) 1.7. **Mindfulness** 1.7.1. Mindfulness Attention Awareness Scale 1.8. **Experiential Avoidance** 1.8.1. Acceptance and Action Questionnaire (AAQ)
2. Aerobic Capacity 2.1. Maximal aerobic capacity (VO2peak) 2.1.1. Graded treadmill test to voluntary fatigue with indirect calorimetry
3. Muscular Strength 3.1. One Repetition Maximum (1RM) (seated leg press, unilateral knee extension, chest press, and seated row)
4. Nutrition 4.1. Short Form Food Frequency Questionnaire (SFFFQ) 4.2. CanaCare Dietary Questionnaire
5. Physical Performance 5.1. 6-minute Walk Test (6MWT) 5.2. Short Physical Performance Battery 5.3. Balance (static and dynamic)

6. Anthropometry

6.1. Waist, upper-arm and calf circumference (cm)
6.2. Height (cm)
6.3. Weight (kg)

7. Body Composition

7.1. Whole body and regional lean and adipose tissue, Bone density in the lumbar spine and hip - Dual-energy X-ray absorptiometry (DXA)

8. Sleep Quality

8.1. Subjective sleep quality
Pittsburgh Sleep Quality Index (PSQI)

9. Health Status

8.1 Past medical history

Past medical diagnosis and symptoms (physical, mental or emotional), past treatments, medications, past falls.

8.2 Ongoing health status

New medical diagnosis, new (or change) in symptoms, new (or change) in medications, falls, visits to health care practitioners. Gathered using a weekly health check questionnaire

10. Adherence to Intervention

10.1. All adverse events related and not related to the intervention. Gathered using weekly health status check and reporting of events throughout the study period.

11. Cognitive Function

11.1. Montreal Cognitive Assessment (MoCA) score

12. Haemodynamic Measures

12.1. Blood pressure
Resting, orthostatic

13. Alcohol-related Outcomes

13.1. AUDIT-C

14. Physical Activity Levels

14.1. Subjective physical activity
Paffenbarger Physical Activity Questionnaire
Physical Activity Scale for the Elderly

15. Metabolic

15.1. The Australian Type 2 Diabetes Risk Assessment Tool (AUSRISK)

10. DATA MANAGEMENT

Electronic copies of information will be stored in two places:

1. CIA Prof. Maria Fiatarone Singh's Research server maintained by the University of Sydney. This carrier will be used to store contact information, progress databases, digital copies of consent forms, medical letters, audio and video recordings, and correspondence and manuals of procedures. This is a password protected server only accessible to researcher involved in the project. Server back-up is performed by the university central server. All documentation will be password protected.

2. REDCAP Digital. REDCap is a secure web application hosted by The University of Sydney for building and managing databases. All data entered into the database will be stored on a secure server of the University of Sydney. As such, no project data is ever transmitted at any time by REDCap to another institution.

Access to the database will be provided only to research staff working on the study. User privileges will be used to limit the viewing and/or editing access that research members have within the database. Data will be retained for 15 years, consistent with the Australian Code for the Responsible Conduct of Research, after which all data will be destroyed. Ethics approval will be sought to retain data beyond this period.

11. TIMELINES / MILESTONES

Table 2 illustrates the expected project timeline.

Table 2. CanaCare study timeline.

Study duration: 3 year (2020-2022)	It is expected that the study will be carried out over a 3-year period.
June – July 2019:	Study protocol will be drafted, and ethics approval obtained.
August 2020:	Clinical Trial Risk and Governance documentation will be completed and submitted for approval.
September2020:	Recruitment will begin in September 2020.
September 2020– September 2023:	It is expected that study will run for the course of 3 years.
November 2023-May 2024:	Publications in appropriate scientific journals and dissemination of results will be prepared in early 2022 – late 2022.

12. FINANCIAL

The CanaCare program will be provided on an entirely voluntary basis to participants by health care professionals and other volunteers, and will be assisted by students who are completing HDR degrees or undergraduate/postgraduate placement hours for USYD degrees. The study is also partially supported by the Seed Funding Scheme: Mental Health, Drug and Alcohol Comorbidity" from the University of Sydney and University of New South Wales. Money from the grant had been used to purchase pin-loaded strength training equipment that is now stored at Cana Farm in Orchard Hills.

13. PUBLICATION POLICY / DISSEMINATION OF RESULTS

Primary and secondary outcomes from the study will be published in appropriate scientific journals. All scientific papers, including authorship will be agreed upon by consensus by the study investigators.

Dissemination of results will also occur by presenting results at scientific conferences, and in presentations to the public. In addition, participants may elect to receive a one-page summary of the study findings.

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