Protocol: The effect of individual Cognitive Stimulation Therapy delivered by trained volunteers on cognition and quality of life in people with mild to moderate dementia: A pilot randomized controlled trial

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INTRODUCTION

Cognitive stimulation is defined as "engagement in a range of activities and discussions (usually in a group) aimed at general enhancement of cognitive and social functioning" [1]. Cognitive stimulation therapy (CST) is a structured and manualised group treatment specifically developed for people with mild to moderate dementia. It involves 14 or more sessions of themed activities [2]. They were designed to run twice a week over a seven-week period. Sessions are aimed to actively stimulate and engage people with dementia, while providing an optimal learning environment and the social benefits of a group. The effects of CST appear to be of a comparable size to those reported with the currently available anti-dementia drugs [3]. A cost effectiveness study found that CST for people with dementia may be more cost-effective than usual treatment [4]. CST was developed in the UK and recommended in the NICE dementia guidelines [5]. It has been adopted in 24 countries including New Zealand. A recent Cochrane review concludes that cognitive stimulation programmes can benefit cognition in people with mild to moderate dementia over and above any medication effects, while the improvements in self-reported quality of life and well-being were promising. [6]

Individual CST (iCST) is a novel home-based approach to deliver CST. There has been only one previous study on iCST which was delivered by family carers. [7,8] The study did not find any significant difference in the primary outcomes (cognition and quality of life for people with dementia, and quality of life for their carer). However, it found people with dementia (PWD) had better quality of relationship with their carer who delivered the programme and carer had better health-related quality of life and less depression.

We are currently completing an iCST feasibility study in partnership with Dementia Auckland (formerly Alzheimers Auckland). This feasibility study is due to complete in August 2017 but so far we have found:

(i) Dementia Auckland had successfully recruited a pool of volunteers to deliver iCST. And indeed, there was an overwhelming support from young people who are willing to support people with dementia. For example, we recently trained 17 volunteers in a 1-day iCST workshop for Dementia Auckland and 80% of them are undergraduate health science students (e.g. psychology) from the University of Auckland; the other group of volunteers are those who have recently retired.

(ii) It is feasible to train both Dementia Auckland Keyworkers (registered health professionals) and volunteers to deliver iCST twice a week for ten weeks (a total of 20 sessions) at home. Keyworkers and volunteers were trained in a 1-day workshop and received ongoing support from the research team.

(iii) It is feasible to recruit a sufficient number of participants with mild to moderate dementia through Dementia Auckland. 27 people with mild to moderate dementia (Montreal Cognitive Examination≥10) were recruited over a 6-month period.

(iv) The feasibility study was approved by the Health and Disability Ethics Committee (HDEC). We have successfully worked through the ethical implications with the HDEC when consenting people with dementia for an intervention trial.

(v) We included a computerised neurocognitive assessment as one of the outcome measures. However, most participants found this assessment too cognitively demanding and struggled with it. We will not include this computerised assessment in this pilot study.

AIM

This pilot study will build on the work we have already completed on testing the feasibility of delivering iCST for people with dementia by trained volunteers. The aim is to recruit a larger sample that will allow power calculation for a future multi-centre trial comparing the efficacy of iCST delivered by trained volunteers with treatment as usual (TAU). The null hypothesis is that when compared to treatment as usual, iCST (delivered by trained volunteers) has no positive benefit on cognition or quality of life for people with mild to moderate dementia.

STUDY DESIGN

This pilot study will comprise two arms to compare 1) iCST delivered by Dementia Auckland trained volunteers and 2) treatment as usual (TAU).

Setting and participants:

Participants will be living in the community in their own home including those residing in a retirement village.

Inclusion criteria:

1. People aged ≥50 years with a diagnosis of mild to moderate dementia (Montreal Cognitive Assessment score of 10 or more).
2. The person can have a 'meaningful' conversation.

3. The person can hear well enough to participate in a 1-to-1 discussion.
4. The person's vision is good enough to see most pictures.
5. The person is likely to remain in a session for 45 minutes

Exclusion criteria:

1. Those within the past 6 weeks who have had a recent acute medical illness such as stroke or heart attack.
2. Those who is currently participating in a cognitive stimulation treatment

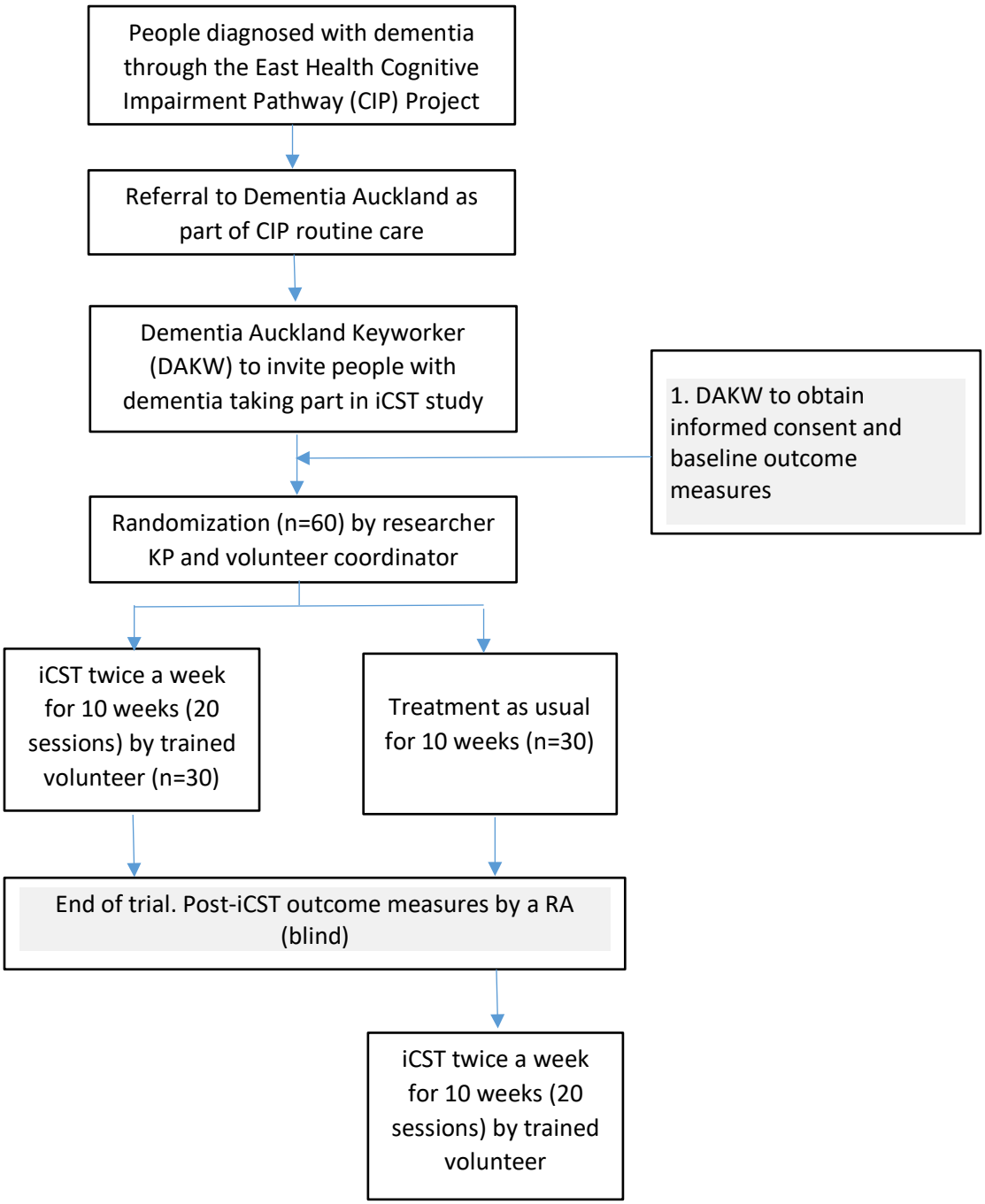
Recruitment of participants:

Figure 1 shows the study flow-chart.

Potential participants and their family carers are new referrals to Dementia Auckland by the general practitioners (GPs) in East Health Primary Health Organisation (PHO). GPs in East Health PHO are involved in a new initiative using the Auckland Regional Cognitive Impairment Pathway that promotes early diagnosis and management of dementia in primary care which includes referring people with dementia and their family to Dementia Auckland for psychoeducation and support.

Keyworkers of Dementia Auckland will invite potential participants to join this study by providing them and their carer with a participant information sheet. Interested parties can then approach their keyworker who can contact the research assistant and to be enrolled in the study.

Figure 1: Study flow-chart



Sample size and randomisation:

60 Participants will be randomised into one of the 2 arms: (i) iCST delivered by Dementia Auckland volunteers trained by the research team; and (iii) TAU.

iCST will be delivered at home twice a week for 45-minute per sessions for 10 weeks.

Participants who are randomised to the TAU group have the option to receive iCST or group CST at the end of the trial.

There is no power calculation as the aim of this pilot is to generate data for the estimation of sample size in a future multi-centre randomised control trial.

Informed Consent:

Informed consent will be obtained from competent participants. For participants who lack capacity to provide informed consent, their next of kin's view will be sought in accordance to the Code of Health and Disability Services Consumers' Right 7(4). In addition, the clinician who enrolled a participant who lacks capacity will verify that it is in the *best interest* of the participant to take part in the study.

Intervention:

(i) The iCST programme (delivered by trained volunteers)

The iCST facilitator has completed the one day master class iCST training delivered by members of the research team.

The iCST programme is:

15 minutes warming up, orientation, current affairs, refreshments and gentle stretches

20 minutes of the iCST activity

10 minutes warm down, discuss topic for following session

TOTAL 45 minutes

The key principles of iCST are

1. Mental stimulation
2. Developing new idea, thoughts and associations
3. Using orientation in a sensitive manner
4. Focusing on opinions, rather than facts
5. Using reminiscence as an aid to the here and now
6. Providing triggers to support memory
7. Stimulate language and communication
8. Stimulate every day planning ability
9. Using a “person-centred” approach
10. Offering a choice of activities
11. Enjoyment and fun
12. Maximising potential
13. Strengthening the relationship by spending quality time together

(ii) Treatment as Usual (TAU)

People allocated to the treatment as usual arm will receive routine follow up by Dementia Auckland. For a new referral to Dementia Auckland, the keyworker usually completes 4-6 home visits within the first six months to provide practical strategies for the carer/family. The Keyworker will refer the carer to Carer Education if this is a carer preference. The keyworker can refer the person with dementia (PWD) to the Socialisation service for community based group activities. The keyworker will integrate the carer into monthly support groups. Following the initial six months, there are regular phone calls, home visits if required, support groups and Socialisation. Each person is re-assessed with a home visit annually.

Data Collection:

(i) Baseline demographics (age, gender, ethnicity, marital status, education), medical conditions, medications and living arrangement

(ii) Outcome measures -

The following outcome measures will be collected at baseline and post-intervention (in 10 weeks). The Dementia Auckland Keyworker will collect the baseline data, along with informed consent. Randomisation will follow the completion of baseline measures. A blinded research assistant will collect the post-intervention data.

Person with dementia: Montreal Cognitive Assessment (MoCA)*; World Health Organization Quality of Life (WHOQOL)*;

(* indicates primary outcomes)

Carer of the person with dementia: Caregiver burden (Carer Reaction Assessment) and WHOQOL.

Statistical Analysis:

ANOVA will be used for comparing the pre- and post-outcome measures in the two intervention groups and treatment as usual group. Significant will be tested at 5%.

Training and support:

The iCST training will be delivered by GC and KP who are the New Zealand master trainers in CST. The one day group training session will focus on the key principals of CST and problem solving strategies relevant to iCST.

The training session will also include viewing clips of good practice in CST from the Making a Difference 3 training digital video disc (DVD). A practical iCST session will be conducted during the day to allow learners to deliver a session and be peer reviewed.

At the completion of the training day iCST facilitators will be provided with a iCST manual, activity workbooks and additional resources such as a deck of cards, laminated pictures, world and NZ maps.

iCST facilitators will receive support (as required) from the research team and coordinators at Dementia Auckland. The research team will provide monthly group supervision for the iCST facilitators during the course of the study. These sessions will address issues arise from the study and provide coaching for delivering the therapeutic intervention.

Dementia Auckland will provide petrol vouchers for volunteers visiting participants at home.

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