An Individual Cognitive Stimulation Therapy Application (iCST app) for People With Dementia and Carers: Protocol for a Feasibility Randomized Controlled Trial.

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Abstract

Background: There is a need for more resources to support the cognition and quality of life (QoL) of people with dementia. The individual Cognitive Stimulation Therapy application (iCST app) aims to provide cognitive stimulation and social interaction to people with dementia and carers through interactive touch-screen technology. It has been developed according to the principles of CST and iCST which have previously shown to improve the cognition and QoL of people with dementia, and to benefit the relationship between the person with dementia and carer, while improving quality of the carer's life. This study aims to evaluate the feasibility of conducting a full-scale, randomized controlled trial (RCT) with the iCST app.

Objective: To evaluate the feasibility of conducting a full-scale RCT with the iCST app compared to a treatment as usual (TAU) control group.

Methods: A multi-centre, pragmatic, single blind, feasibility RCT with a treatment as usual (TAU) control group. This study aims to recruit 60 people with mild to moderate dementia and their informal carers as dyads. Both parties must be able to provide informed consent and participate in the intervention. Dyads will complete a baseline assessment which will include cognition and QoL measures, and will subsequently be randomized (1:1) to the iCST app intervention in addition to usual care, or to usual care only. All participants will be followed-up at 5 weeks and 11 weeks post-baseline. A range of feasibility outcomes will be assessed including recruitment and retention rates, intervention fidelity and usability, and acceptability of the outcome measures. A sample of the experimental group will be invited to a semi-structured post-trial interview to further examine the experience of using the iCST app.

Results: Recruitment began in November 2018 with 43 dyads recruited from primary and secondary care settings. Participants were randomized to the iCST app (n = 21) or TAU control group (n = 22) with a relatively low attrition rate throughout the study (n = 2). Dementia support groups and (online) research databases led to the majority of the referrals for the study.

Conclusions: This study will investigate whether it is feasible to conduct a full-scale RCT to evaluate the clinical effectiveness of the iCST app in comparison to usual care alone. In addition, it will further examine the usability of the iCST app. The data will provide information on potential modifications to be made to the intervention, study design, and study process. Clinical Trial: ClinicalTrials.gov, NCT03282877. Registered on 19 July 2017.

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Title: An Individual Cognitive Stimulation Therapy Application (iCST app) for People With Dementia and Carers: Protocol for a Feasibility Randomized Controlled Trial.

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Trial registration: ClinicalTrials.gov, NCT03282877. Registered on 19 July 2017.

Keywords

Dementia, Cognitive Stimulation Therapy, touch-screen technology, feasibility trial.

Background

Dementia poses a significant challenge to individuals in staying mentally stimulated and engaged. This is further exacerbated given the lack of resources to support the cognition and quality of life (QoL) for people with dementia. Cognitive Stimulation Therapy (CST) is a non-pharmacological treatment strongly recommended by the National Institute for Health and Care Excellence. A previous randomized controlled trial (RCT) showed it can benefit the cognition and QoL of people with dementia [1]. Individual CST (iCST) is delivered by a carer at home and has shown improvements in the relationship quality between the person with dementia and carer, and the QoL of carers [2]. Touch-screen technology can improve accessibility to interventions by offering these on devices such as mobile phones and tablets. A systematic review has shown that touch-screen interventions with sound designs and tailored content can improve the well-being of people with dementia [3].

Researchers have developed a novel, touch-screen iCST application (app) which aims to offer cognitive stimulation to people with dementia at home using touch-screen technology. It is hoped that the iCST app may produce combined benefits of engaging in CST, iCST and touch-screen technology. The app's development followed the Medical Research Council Framework for developing complex interventions and the Centre for eHealth Research roadmap [4, 5]. This included extensive reviews of CST and iCST materials, and end-user involvement through informal

consultations, focus groups, individual interviews, and usability questionnaires [6]. The next stage of development encompasses this feasibility RCT. Findings from this study will inform whether a large-scale RCT evaluating the clinical effectiveness of the iCST app is indicated by investigating relevant study parameters related to the study design and process.

Aims

The aims of this feasibility RCT are to:

(1) to evaluate the feasibility of conducting a full-scale RCT with the iCST app compared to a treatment as usual (TAU) control group and,

(2) to assist the development of a protocol for a full-scale trial, including power analysis.

Methods

The 26-item Consolidated Standards of Reporting Trials (CONSORT) checklist of information to include when reporting feasibility trials will be used for this study to ensure all the necessary and relevant information is reported [7]. The study was registered with ClinicalTrials.gov on 19 July 2017 (registration number: NCT03282877).

Study Design

This study is a multi-centre, pragmatic, single blind, feasibility RCT with an allocation ratio of 1:1. People with dementia and carers will be recruited as dyads and will be randomized to either the experimental (completing 2 to 3, 30-minute iCST app sessions per week) or the TAU control group for 11 weeks. Dyads will complete the baseline assessment prior to randomization and hereafter, the first follow-up (FU1) will be completed 5 weeks post-baseline, and the second follow-up (FU2) 11 weeks post-baseline (Figure 1). A sample of the experimental group will be invited for a semi-structured post-trial interview to gain insights in the acceptability of the iCST app including the experience of using the app, and any facilitators and barriers for implementation in daily life.

Participants

Recruitment started on 1 November 2018 and will take place in 5 secondary care settings in England: Derbyshire Healthcare NHS Foundation Trust, Leicestershire Partnership NHS Trust, Lincolnshire Partnership NHS Foundation Trust, Northamptonshire Healthcare NHS Foundation Trust, and Nottinghamshire Healthcare NHS Foundation Trust. In addition, participants will be identified through a variety of settings including general practitioner (GP) practices, community mental health teams, memory clinics, care homes, memory cafes, support groups, and voluntary sector organisations such as the Alzheimer's Society. Remote recruitment will include registration on the website Join Dementia Research (JDR), publicizing the study using social media platforms such as Twitter, and the distribution of information leaflets and posters to organisations and professionals involved in the identification of possible participants.

Eligibility Criteria

The sample will include people with mild to moderate dementia and their informal carers (relatives or friends). The inclusion- and exclusion criteria were adapted from previous CST and iCST research [1, 2] and include the following:

Person with dementia:

- Meet Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) criteria for dementia [8].
- Score 10 or above on the Mini Mental State Examination (MMSE) [9] or score of 16 or above on the Montreal Cognitive Assessment [10] where available.
- Some ability to communicate and understand (eg, ability to give informed consent).
- Ability to speak and understand English.
- See/hear well enough to participate.
- No major physical illness or disability affecting their participation.
- Age range: 50 years – no maximum age limit.
- Availability of a touch-screen tablet for the person with dementia and carer.

- Availability of a carer (or relative/friend) to participate in the activities.

Carer:

- Minimum age: 21.
- Ability to speak and understand English.
- See/hear well enough to participate.
- No major physical illness or disability affecting their participation.

Exclusion criteria person with dementia and carer:

- Concurrent participation in any other interventional study for people with dementia/carers.

Sample Size

A formal sample size calculation is not appropriate for a feasibility trial. A previous audit of trials registered in the Clinical Research Network (CRN) database in the UK found that most feasibility and pilot trials had a median of 30 or 36 participants per arm and the researchers recommend an upper limit of 60 participants for a feasibility trial [11]. Therefore, a target of 60 dyads is set for this study leading to 30 dyads per treatment arm.

Procedure

Screening for Eligibility

Anticipating logistical support from the National Institute for Health Research CRN East Midlands, it is expected that staff members at each research site will check the eligibility of referrals received from clinicians and staff at the recruitment sources. Participants fulfilling the inclusion criteria will be sent a participant information sheet containing full details about the study. If the dyad is interested in participating, they will be recruited into the trial and a date for the baseline assessment and consenting will be set by the CRN staff member.

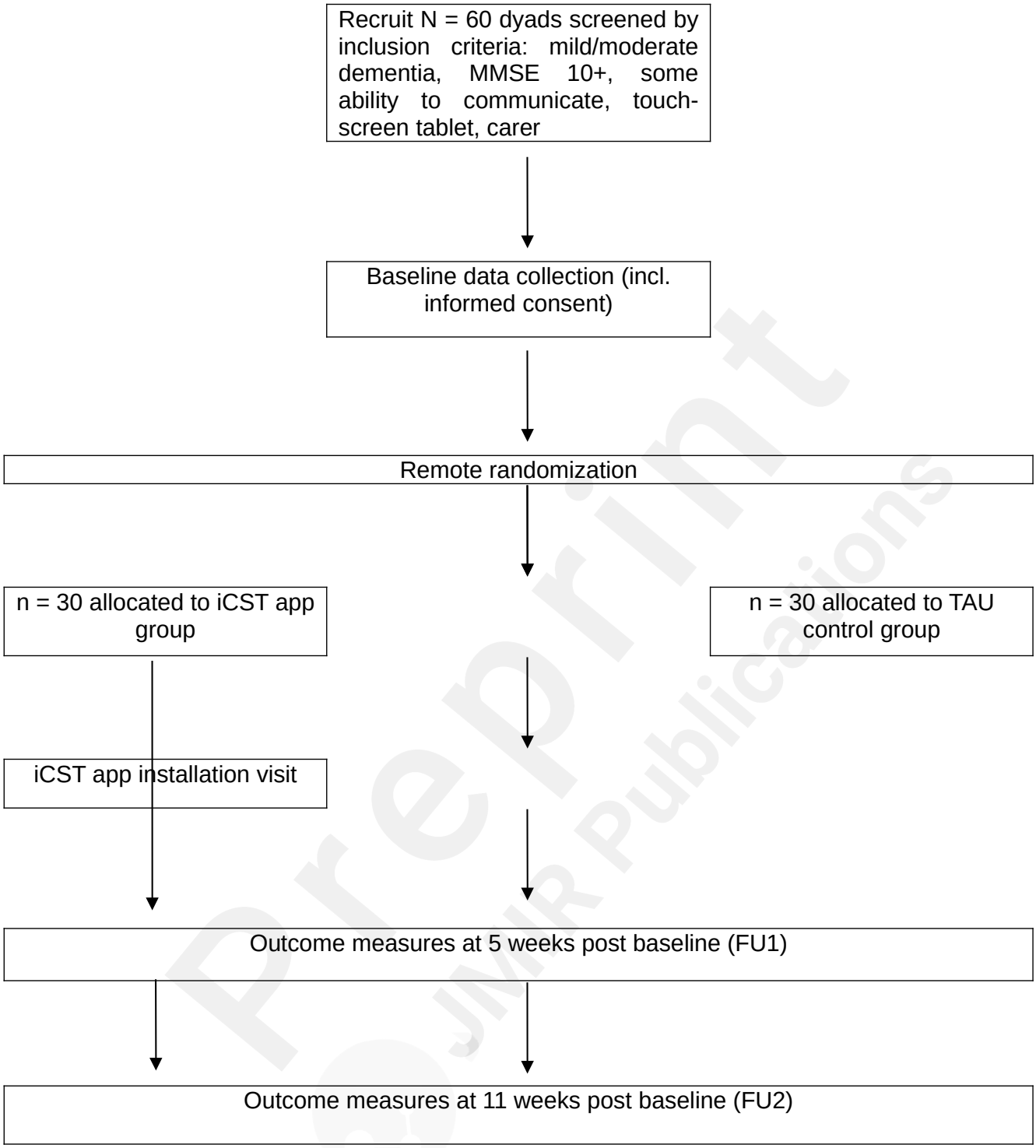


Figure 1. Flow diagram of iCST app feasibility RCT.

Randomization

Randomization will take place after consent and the baseline assessment using an online, central randomization service called Sealed Envelope (https://www.sealedenvelope.com/). Block randomization will be employed with block sizes of 4 to 6 (randomly varied and generated by Sealed Envelope) which is a useful method for small sample sizes to allocate an equal number of participants to each treatment arm [12]. The researcher at the local site will perform each randomisation using the participant identification code of the person with dementia only. The allocation to the experimental or TAU control group will automatically apply to the carer as well. Dyads will be informed of their allocation outcome over the telephone and, if necessary, a visit will be arranged for dyads in the experimental group to install the iCST app.

Blinding

The trial will include both blinded and unblinded researchers at each local site. It is not possible to blind the participants to their treatment arm as the iCST app is a non-pharmacological intervention. However, each study site will include at least one researcher kept in ignorance of study allocations. The baseline assessment can be performed by either researcher. However, FU1 and FU2 will be completed only by the researcher who is unaware of the randomization outcome for each dyad. If disclosure does occur, this will be recorded by the visiting researcher along with details on how it occurred. The unblinded researcher will perform the randomization, communicate the outcome with the participants, and for the experimental group, install the iCST app, provide weekly telephone support calls, and complete the usability and acceptability questionnaire at the end of the study. Furthermore, the unblinded researcher will not be informed about the results of the assessments.

The Intervention: iCST Application

Participants in the experimental group will use the iCST app (prototype v3.0) over 11 weeks post-baseline. The content of the app was modified from the paper-based iCST manual including the principles, themes, and activities [2], and was also based on consultations and qualitative research

with people with dementia, carers, and the software development company [6]. The iCST app is a one-to-one, carer-led, home-based program of structured cognitive stimulation for people with dementia but delivered on a touch-screen tablet. It includes 21 activities consisting of both game-like, interactive features such as audio-visual stimuli, and discussion questions (Table 1). This was to offer mental stimulation through the content on the app but also through conversation.

Table 1. List of the iCST app activities (prototype v3.0)

Game	Discussion	Game and discussion
Being Creative	Past Events	Sounds
Spaceman	Useful Tips	Odd one Out
Trivia Quiz	My Life	The Price is Right
Word Search	Arts	Globe Trotter
Sudoku	Old Wives' Tales	Food
Being Active	Toys Are Us	In Pairs
Brainstorm		Sayings
		ISpy

In addition, the app includes several other features such as a short introduction section explaining the background and key tips for using the app, a home screen which features completed activities, and a choice from 2 levels. Level 2 contains either more challenging content or different questions from Level 1, and it is up to the participants to determine which level they feel more comfortable with for each activity. Figure 2 contains screenshots of the iCST app. Considering previous CST and iCST research and findings from the development work, it is recommended that participants use the app for 2 or 3 times a week for 30 minutes [2]. Participants are free to spend more time on the app if they wish, and this will be recorded during the weekly telephone calls.

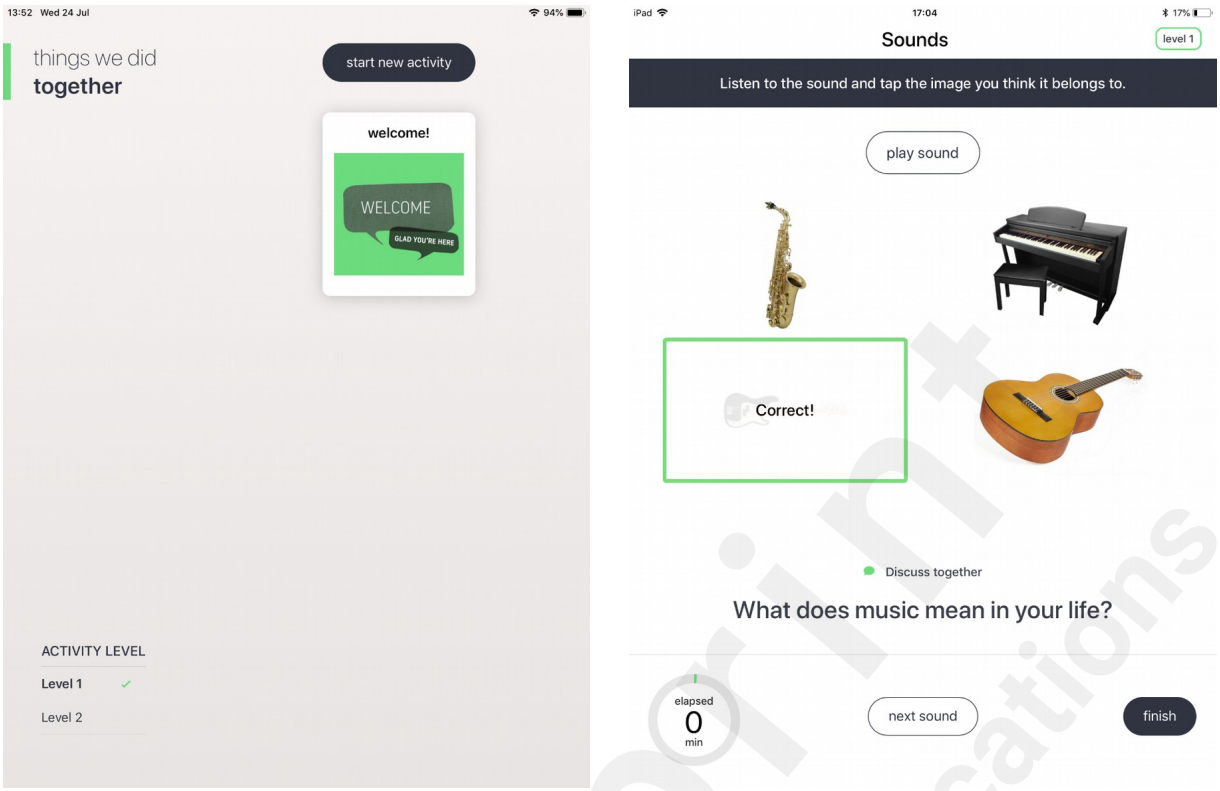


Figure 2. Screenshots of the iCST app: home screen (left) and Sounds activity (right).

Training and Adherence

In order to ensure treatment integrity for all participants, individual study sites will receive a demonstration of the iCST app along with training in its installation and use prior to the start of recruitment. Dyads in the experimental group will receive an in-home visit from the unblinded researcher who will install the app and explain how it works using a short, supplementary document containing instructions with screenshots of the app. Furthermore, all dyads will receive weekly telephone support calls from the same unblinded researcher in order to monitor adherence but also to track overall progress and any challenges or technical difficulties with using the iCST app. Phone calls will be completed with the carer and all questions will be included on a standardised telephone sheet. The questions relate to general experience, amount of sessions completed in a week (on average), amount of time spent per session (on average), enjoyment, and any likes/dislikes. Any reasons for not being able to use the iCST app over the week will also be recorded on the telephone

sheet.

Treatment as Usual (TAU)

The control group will consist of TAU group and will not receive any additional interventions. TAU groups are typically used to compare experimental interventions to care which participants already receive in practice [13]. Therefore, the TAU control group will enable us to compare the effects of the iCST app with the natural progression of people with dementia under conditions of usual care.

The treatments and services which are already available to people with dementia and their carers randomized to the TAU control group, may differ between and within recruitment sites for instance, regarding acetylcholinesterase inhibitors (AchEIs) or being involved in some form of cognitive stimulation already. However, it is unlikely that people have access to computerized versions of iCST since these do not exist to the best of our knowledge. The visiting researcher will record any current participation with CST groups and use of AchEIs at the baseline assessment.

Outcomes

Feasibility Outcomes

In order to determine the feasibility of conducting a full-scale RCT with the iCST app in the future, this trial will investigate key feasibility aspects including the rates of recruitment, screening, randomization, and retention using enrolment logs [4]. Acceptability of the outcome measures will be evaluated by assessing the completion rates, and the acceptability and fidelity of the iCST app will be evaluated through weekly telephone support calls, analytics, and a usability and acceptability questionnaire. It is expected that >75% of the participants in the experimental group will need to complete the recommended minimum of 2 activities on average every week for the iCST app to be considered feasible. This benchmark has been adopted based on work in some previous feasibility trials including psychological treatments where benchmarks for successful adherence ranged between 75% to 80% [14, 15].

Clinical Outcomes

Previous CST and iCST research, and the Interdem consensus statement on outcome measures for

dementia informed the outcome measure selection for this study [16]. Key outcome measures of interest for the person with dementia are cognition and QoL as previous CST research has shown improvements in these domains [1]. For the carer, the key outcome measure is QoL as previous iCST research has shown to improve the QoL of carers [2]. This study additionally includes technology-related scales to assess usability and acceptability of the iCST app and computer use self-efficacy. All assessments will take place in the homes of the participants. Wherever possible, 2 researchers will visit the participants in order to interview the person with dementia and carer separately. It will be possible to conduct the assessments over 2 days in case of fatigue or other practical issues such as lack of time. As in the previous iCST trial, FU1 at 5 weeks will be included to safeguard data against loss to follow up [2]. FU2 will take place at 11 weeks post-baseline as this should be the point that participants in the experimental group will have completed each activity on the iCST app.

Outcome Measures for Person With Dementia

- Cognition measured using the Alzheimer's Disease Assessment Scale-Cognition [17].
- QoL measured using the Quality of Life – Alzheimer's Disease (QoL-AD) questionnaire [18]. Carers will complete the family version of the QoL-AD.
- Health-related QoL measured using the EuroQoL five dimensions (EQ-5D) questionnaire [19].
- Relationship quality measured using the Quality of the Carer Patient Relationship (QCPR) questionnaire [20].
- Symptoms of depression measured using the Cornell Scale for Depression in Dementia [21]. Carers will complete this questionnaire as an informant.
- Behavioral disturbances measured using the Neuropsychiatric Inventory and will be rated by the carer only [22].
- Functional abilities measured using the Bristol Activities of Daily Living Scale [23] and rated by the carer only.

Outcome Measures for Carers

- Health-related QoL measured using the EQ-5D questionnaire [19].
- Anxiety and depression measured using the Hospital Anxiety and Depression Scale [24].
- Relationship quality measured using the QCPR questionnaire [20].

Technology Scales for People With Dementia and Carers

- Self-efficacy beliefs in computer/tablet use measured at baseline only using the Computer User Self-Efficacy scale [25].
- Usability and acceptability of the iCST app measured at FU2 and among the experimental group only using the Questionnaire of Usability and Acceptability (CUA) [26].

Post-trial Interviews

A small proportion of dyads in the experimental group will be invited to participate in joint, semi-structured interviews. The purpose of the interviews is to gain additional information on the layout and content of the iCST app, the overall experience of using it as a dyad, and any practicalities surrounding its use in daily life. The interview serves as a complementary data collection method to the weekly telephone support calls and the usability questionnaire as a semi-structured interview generates more in-depth data that otherwise cannot be accessed through quantitative methods only [27]. A discussion guide will be developed including the key areas mentioned before to help guide the interview. Each dyad in the experimental group will be invited to participate in the interview upon completion of the study. If they are interested, further details for the person with dementia and carer will be sent. If a dyad agrees to participate, a date for the interview will be set. All interviews will take place in the home of the participants. Written informed consent will be obtained from both participants by the unblinded researcher. The data will be audio-recorded, transcribed, and subsequently stored on a password protected computer at the University of Nottingham.

End of Study

FU2 constitutes the end of the study for participants. At this final visit by the blinded researcher, all participants will be given a £10 Apple or Google Play store voucher in order for them to download

the iCST app once it has been released on the app stores. This will be accompanied by an instructional document on how to redeem your voucher and a newsletter containing information on what will happen next such as making improvements to the app, and analyzing and disseminating the results.

Ethical Considerations

Ethical approval has been obtained from the Yorkshire and the Humber – Bradford Leeds Research Ethics Committee and NHS Health Research Authority in March 2018 (reference number 17/YH/0405).

Consent

People with mild to moderate dementia will be recruited in the study and are expected to be able to give informed consent for participation provided that appropriate care is taken in explaining the research and sufficient time is allowed for them to reach a decision. Written informed consent will be taken at baseline from both the person with dementia and carer. Since the intervention requires joint participation, it is likely that both participants will consult each other in making their decision. Therefore, it is possible that any individual participant's decision to either participate or not participate with the research may be influenced by the other participant. However, it is important that individual participants are not forced to make a decision against their will and the researcher will spend as much time as necessary in speaking to the participants individually about the research. It will be made clear to both people with dementia and carers that no disadvantage will accrue in terms of the current care they receive or any future research opportunities, if they choose not to participate or withdraw from the study. The consent form will be signed and dated by the participant and the researcher before they enter the study. One copy will be given to the participant and one will be retained at the local study site.

Adverse Events

Previous work with CST, MCST, and iCST has not documented any harmful side effects nor any serious adverse events from participating in the intervention activities [1, 2, 28]. Given that the iCST

app is based on the principles of CST and follows a comparable structure to iCST, it is expected that this study will not lead to harmful side effects for either the person with dementia or the carer. Researchers will be made aware of any adverse events during follow-up assessments or the weekly telephone support calls. The trial manager and chief investigator of the study will be informed in case of any adverse events who will then assess the severity of the adverse event. Serious adverse events include events such as death, illness related to a previous health condition, or hospitalisation.-

Data Security and Entry

Each study site will create their own password-protected spreadsheet containing participant identifiable information and allocation outcome for the dyad. This spreadsheet can only be accessed through a secure NHS trust computer. After collection of the data from each site, the data will be stored in a secure cabinet at the University of Nottingham. Identifiable information including the consent forms will be kept in a separate, locked cabinet. After reviewing the data and checking the scoring, it will be entered manually into SPSS version 25 for Windows, which will be used for all the analyses.

Statistical Analyses

Key feasibility outcomes will be reported through frequencies and include the number of participants screened, recruited, randomized, and retained through the duration of the trial. Adherence to the intervention will be assessed by calculating the average number of iCST app activities completed by the dyad logged in the weekly telephone calls. The usability and acceptability of the iCST app will be further investigated by examining data from the weekly telephone calls, post-trial interviews, and by calculating scores on the CUA with higher scores indicating higher levels of usability and acceptability. Data from the post-trial interviews will be coded and summarised and may be analysed thematically with specialised software if sufficient data has been obtained to reach data saturation [29]. Lastly, outcome measures will be assessed for appropriateness by calculating missing data rates within the measures and across the follow-ups.

As this is a feasibility trial and null hypothesis significance testing is inappropriate due to a likely lack of power to detect significant effects of the intervention [30-32], analyses will mainly include descriptive statistics computed for each group and outcome measure including means, standard deviations, 95% confidence intervals and effect sizes [7, 33]. However, in order to compare the outcomes on each of the questionnaires between the two groups, an analysis of covariance will be undertaken which will help to better understand any trends in the data. All analyses will be based on the intention-to-treat principle in that all available data will be included in the analyses. Rules for missing data will be adapted from the main iCST trial [2]. Data will not be imputed if outcome measures or assessments are missing in full, and imputation (using pro-rating) will only be used when fewer than 20% of cases are missing on any given measure.

Results

Recruitment

A total of 384 dyads have been approached or referred across 4 research sites and, of these, 43 dyads have been consented, gave completed the baseline assessment and were randomized to either the iCST app or TAU control group. Table 2 includes the response rates and the total numbers of participants lost before randomization accompanied by reasons for loss. Most frequently, the reason for not recruiting a dyad to the trial was unknown as not all sites registered dyads' reasons for not participating with the study (eg, when visiting support groups in particular). In most other cases, the lack of having a correct device for the study and the remaining study exclusion criteria led to dyads being ineligible. Participants who did not have the correct device, often did have access to technology such as personal computers, laptops, and mobile phones but not a device compatible with the iCST app such as a tablet with iOS version 10 or Android version 4.4.2.

Table 2. Response rates and loss of participants prior to randomisation.

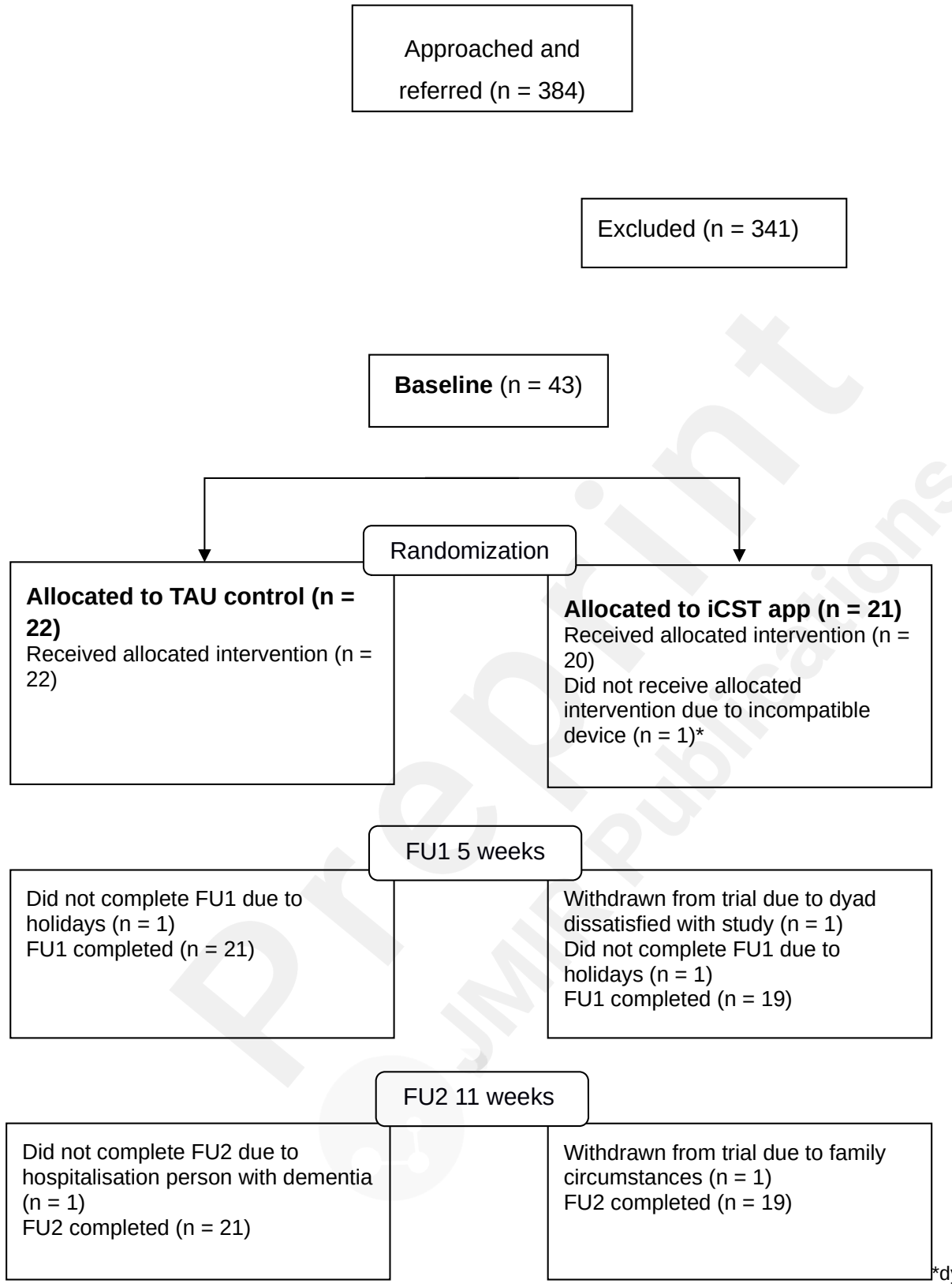
Reason	Total (%)
Total approached/referred	384
Reason unknown or not disclosed	100 (26)
Exclusion criteria applied	90 (23)
Lack of availability correct device	80 (21)
Does not wish to take part	52 (14)

Dyad approached has not responded	14 (4)
Not interested in using technology	5 (1)
Total lost between approach/referral and randomization	341 (89)
Total number randomized	43 (11)

Participants were most often referred from or approached through dementia support groups (n = 162), JDR (n = 76), the site's own research database (n = 69), or clinicians working in community mental health teams or memory assessment services (n = 43). A small proportion of participants were approached through their GP (n = 13) or care home promotion (n = 2), and one other participant was referred through a leaflet advertising the study. For 18 participants, the source of referral or approach was unknown.

Participant Flow and Retention Rates

Figure 3 shows the participant flow through the feasibility trial along with treatment allocation, number of withdrawals, and non-completion of either FU1 or FU2 per allocation group [7]. Block randomization led to an equal distribution of participants across the treatment groups with 21 dyads randomized to the iCST app group and 22 dyads randomized to the TAU control group. One dyad in the experimental group was not able to access the iCST app. All participants accepted their allocation outcome to either the iCST app or TAU control group and no dyads dropped out after learning their randomization results. Furthermore, retention rates were high with only 2 dyads from the experimental group withdrawn from the study.



*dyad who did not receive the intervention in the experimental group was subsequently withdrawn from the study.

Figure 3. CONSORT flow diagram: participant flow through feasibility trial.

Baseline Demographic Data

Tables 3 and 4 show the demographic information of people with dementia and carers. People with dementia overall had a mean age of 73.05 years, and the majority of people with dementia were male (n = 29), married (n = 34) and lived at home with their spouse or partner (n = 36). Half of the people with dementia had no educational qualifications (n = 11) or had left school after their O-Levels/GCE (n = 10). Most people with dementia were taking AchEIs at the time of the baseline assessment (n = 30) with an almost equal distribution across the iCST app (n = 16) and TAU control group (n = 14). Lastly, the majority of people with dementia were not involved in any CST groups at the time of the study (n = 35). Data for 7 people with dementia was missing on at least one demographic.

Table 3. Demographics of people with dementia.

	Total	**iCST app**	**TAU**
Characteristic			
Age in years: mean, SD (range: 50-89)	73.05, 8.41	73.43, 7.81	72.65, 9.20
Male (%)	29 (67)	13 (62)	16 (73)
Ethnicity white (%)	42 (98)	20 (95)	22 (100)
Relationship with carer: married (%)	34 (81)	18 (86)	16 (76)
Lives with spouse/partner (%)	36 (86)	18 (86)	18 (86)
Education: no qualifications or School Leaver O-Levels/GCE (%)	21 (50)	12 (57)	9 (43)
Taking AchEI medication (%)	30 (75)	16 (80)	14 (70)

The mean age of carers was 66.21 years and the majority of carers were female (n = 33) and in terms of educational qualifications had either left school after their O-Levels/GCE (n = 14) or had a BSc/BA degree (n = 10). Data was missing for 5 carers on at least one demographic. For both people with dementia and carers, the sample was predominantly white with only one person with dementia from Asian descent. One carer preferred not to disclose their ethnicity.

A total of 34 spousal dyads participated with the study and the non-spousal dyads consisted of partners (n = 2), children (n = 3) or the son/daughter-in-law (n = 1) of the person. Two dyads identified their relationship as ‘other’.

Table 3. Demographics of carers.

	Total	iCST app	TAU
Characteristic			
Age in years: mean, SD (range: 27-83)	66.21, 12.11	68.21, 9.90	64.30, 13.88
Female (%)	33 (77)	16 (76)	17 (77)
Ethnicity white (%)	42 (100)	21 (100)	21 (100)
Education: School Leaver O- Levels/GCE or Higher Education (BSc/BA) (%)	24 (59)	11 (52)	13 (65)

Discussion

Overview

The iCST app is the first computerized version of iCST which can be used on touch-screen tablets by people with dementia and their carers. It aims to provide mental stimulation and to stimulate conversation between dyads through the use of interactive touch-screen technology. Based on previous research, it is expected that regular use of the iCST app could potentially lead to improved cognition and QoL for the person with dementia and carer. This is an innovative feasibility RCT which sets out to evaluate the feasibility of conducting a full-scale RCT with the iCST app compared to a TAU control group, and to assist the development of a protocol for a full-scale trial. A range of data will be collected on relevant study-related aspects for a potential full-scale RCT including the study design and process, and the feasibility and usability of the iCST app. Data collection is supported by a mixed methods approach where quantitative data from questionnaires and analytics will be complemented by qualitative data from telephone calls and interviews with people with dementia and carers.

Preliminary findings indicate that recruitment for the study is feasible but certain challenges related to the technology-related inclusion criteria have been identified (eg, lack of compatible touch-screen tablet for iCST app). Dementia support groups, JDR, and the local research databases have generated the majority of referrals for this study, and may prove to be most useful for recruitment in a larger study. Referral through community mental health teams and memory

assessment services could be improved by more frequent contact and visits to such sites. Findings also suggest that allocation outcome following randomisation is acceptable to participants with a relatively low attrition rate across the two groups. The findings from this feasibility RCT will be used to draw recommendations in terms of conducting a full-scale trial and determine which modifications are necessary. This will be done using the Acceptance Checklist for Clinical Effectiveness Pilot Trials which consists of several trial components ranging from trial design and interventions to randomization and data procedures [34]. It will be used to determine which components of the trial will need amendments and how this can be achieved. In addition to a large-scale RCT with the iCST app, other research activities could consist of an implementation study which would investigate the cost-effectiveness and also the accessibility of the iCST app among people with dementia from varying backgrounds. This could include consultation work with people with dementia and carers in order to explore facilitators and barriers towards accessing technology, the iCST app and its use.

Limitations

This is a national, small-scale study with a limited amount of study sites and participants which means that formal effectiveness of the iCST app cannot be evaluated. However, the study scale and smaller sample size is appropriate for the purpose of a feasibility RCT. The iCST app is only compatible with certain touch-screen tablets and software versions which has proved to be a challenge to recruitment for all study sites. Furthermore, reasons for referral loss were often unknown as not all study sites registered reasons why potential participants were not recruited to the study. Therefore, there is a need for improved monitoring to ensure how referral loss can be minimized for a future full-scale trial.

Conclusion

This study will give insights in the feasibility of conducting a full-scale RCT with the iCST app compared to a TAU control group. Preliminary results show that recruitment is feasible despite some challenges related to the technology-related inclusion criteria. Furthermore, randomization measures are adequate and attrition is low throughout the study. The full results of this feasibility

RCT including data on the intervention in terms of usability and adherence, and outcome data are expected in early 2021. These results will inform whether a full-scale RCT is feasible and which modifications to the study design and process, and intervention are needed.

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Conflicts of Interest

Royalties from the sales of the iCST app (Thinkability) go to Eumedianet and the University of Nottingham and provide support for ongoing maintenance of the app including future updates.

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Abbreviations

AchEIs:	Acetylcholinesterase Inhibitors
App:	Application
CONSORT:	Consolidated Standards of Reporting Trials
CRN:	Clinical Research Network
CST:	Cognitive Stimulation Therapy
CUA:	Questionnaire of Usability and Acceptability
EQ-5D:	EuroQoL five dimensions
FU1:	Follow-up 1
FU2:	Follow-up 2
GP:	General Practitioner
iCST:	individual Cognitive Stimulation Therapy
JDR:	Join Dementia Research
MMSE:	Mini Mental State Examination
QCPR:	Quality of the Carer Patient Relationship
QoL:	Quality of Life
QoL-AD:	Quality of Life – Alzheimer's Disease
RCT:	Randomized Controlled Trial
TAU:	Treatment as Usual