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Evaluating an evidence-based iSupport for Dementia programme in routine care services: study protocol for a hybrid type II trial

Lily Dongxia Xiao ,[1] Ada Cheng,[2] Candy Xie,[3] Kam Chiu,[4] Ying Yu ,[5] Shahid Ullah,[6] Jing Wang,[7] Rujun Hu ,[8] Dingxin Xu,[9] Xiaoying Pan,[10] Angela Rong Yang Zhang[5]

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For numbered affiliations see end of article.

Correspondence to
Dr Lily Dongxia Xiao;
lily.xiao@flinders.edu.au

ABSTRACT

Introduction Disparities in supporting carers of people with dementia exist in carer populations. The WHO developed an evidence-based iSupport for Dementia programme to address the disparities. However, evidence on how to embed the iSupport programme in routine health and aged care services to optimise support for carers remains largely unknown.

Methods and analysis This study will apply a hybrid type II effectiveness-implementation trial to evaluate the embedment of two iSupport innovations: 'usual iSupport' and 'tailored iSupport' in health and aged care services in Australia and China. The RE-AIM framework informed the study design. Three aged care organisations in Australia, two public hospitals and a community health centre in China will participate in the trial by delivering the two iSupport innovations to 158 carers of people with dementia with 79 carers in each intervention group using a randomised controlled trial design. The effectiveness of the two iSupport innovations will be determined by measuring the quality of life and self-efficacy of carers, and the quality of life of people with dementia, unplanned hospital admissions, emergency department presentations and admissions to permanent nursing homes and perceived quality of care of people with dementia at baseline, 3 months and 6 months. The effectiveness of strategies used to embed the iSupport innovations in routine care services will be evaluated using qualitative data collected from focus groups or interviews with carers, staff and management involved in the study and records from the participating organisations.

Ethics and dissemination Ethics approval was obtained from Flinders University (project number: 5819), Xi'an Jiaotong University (project number: 2023–1629) and Zunyi Medical University (project number: KLL-2023–245). We will obtain informed written or oral consent from participants in the trial. We will publish the results in peer-reviewed journals to disseminate the study and generate impact on policy and practice changes.

Trial registration number ACTRN12623000323628; The Australian New Zealand Clinical Trials Registry (ANZCTR); registered on 27 March 2023.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The hybrid type II effectiveness-implementation trial will enable the project team to evaluate the effects of the two iSupport innovations on carers, people with dementia and the organisations while evaluating the strategies used to embed the two iSupport innovations in real care settings.
⇒ This multicentre trial crosses two countries with different care systems and will enable the comparisons of factors affecting the knowledge translation of the iSupport innovations; thus informing the international community of disseminating the iSupport innovations.
⇒ The collection of both quantitative and qualitative data at multiple time points throughout the trial will enable the project team to rigorously evaluate the processes and outcomes of the two innovations.
⇒ As an intervention on health care services in real care settings, we are unable to blind carers in the two iSupport innovation groups. Therefore, a reporting bias may be occurred in this trial.

INTRODUCTION

Worldwide, over 55 million people live with dementia and this number will double in two decades.[1] Of those, 25% live in China and 95% of those in China are cared for by family carers at home.[1 2] In contrast, only 55% of people with dementia (PWD) are cared for by family carers in Western European countries.[1] It is evident that filial piety and Confucianism in Chinese society strongly influence adult children or other family members to look after PWD at home.[3] However, in a recent carer needs assessment survey in Xi'an, a capital city of Shaanxi Province, 73% of carers said that they did not attend dementia care education and the main reasons they described were unawareness of and inability to access the education programme due to paid work or other carer commitments.[4] The study concurs with previous studies in China.[5 6] In the recently issued 'Alzheimer's Prevention and Treatment Promotion Action (2023–2025)' in China, improving support for carers of PWD

has become a national priority.[7] Community health centres (primary care organisations) and hospital memory clinics are in an ideal position to deliver caregiver interventions due to their role in cognitive screening and dementia diagnosis. Despite the policy initiative, evidence on how to embed an evidence-based intervention in routine healthcare services to strengthen support for carers of PWD remains largely unknown.

Australia is a country with one-third of its population born overseas and Chinese-Australians are the largest ethnic minority group, accounting for 1.4 million or 5.5% of the population.[8] Mandarin has become the second most spoken language after English in Australia,[8] an indicator that many carers of PWD speak a language other than English at home and the need to support carers in their preferred language. Moreover, the preference for home-based care in the Chinese diaspora in developed countries, including Australia, has been widely reported, and family carers play a key role in maintaining PWD at home.[6 9] However, in a recent Chinese-Australian carer needs assessment survey study in two states, 88% of carers reported that they did not attend dementia education programmes and the main reason they mentioned was due to the language barrier to accessing the programmes delivered in English.[10] This study supports previous studies that reveal disparities in supporting carers in developed countries.[9 11] Addressing the disparities has become a national priority in the Australian Government's dementia care policies.[12] Ethno-specific aged care organisations (ie, Chinese ethno-specific aged care organisations) that employ staff to match clients' culture and language are in an ideal position to achieve health equity for PWD and their carers.[13] However, evidence on how to embed an evidence-based intervention in routine aged care services to enhance support for carers from the ethnic minority group is scant.

To support the international community in achieving 75% of countries to provide training programmes for carers of PWD by 2025, the WHO developed the iSupport for Dementia programme.[14] The programme is an evidence-based psychoeducation programme for informal carers of PWD. It is underpinned by person-centred care for PWD to meet their care needs and preferences while helping carers reduce stress.[15] The WHO iSupport programme was translated and culturally adapted in the Chinese-Australian community and China through stakeholder consultations between 2019 and 2021.[16 17] The Chinese iSupport programme includes five learning modules to enable carers to learn: general knowledge about dementia; being a carer; performing self-care; performing routine care and preventing and managing changed behaviours. Moreover, the programme also includes useful information about resources and care services relevant for carers to manage dementia at home. The Chinese iSupport manual can be accessed online using the web-based interactive learning; downloaded as an e-book to own computer, iPad or smartphone to use or printed out as a hardcopy manual to use. The Chinese iSupport audiobooks in Mandarin and Cantonese are also available for carers to access via the iSupport website and can be downloaded to own computer, iPad or smartphone to listen to.

The WHO' iSupport programme was mainly implemented as an online self-learning psychoeducation programme and showed inconclusive outcomes in countries that adapted the programme.[18 19] For example, in the randomised controlled trial (RCT) in India, carers in the iSupport intervention group did not show significant improvements in depression, perceived burden scores, carers' self-efficacy, mastery and self-rated health compared with those in the usual care group.[18] In the RCT in Portugal, carers in the iSupport intervention group did not show significant improvement on caregiver burden, depression, anxiety, quality of life (QoL), positive aspects of caregiving and self-efficacy compared with those in the usual care group.[19] A recent systematic review and meta-analyses confirm that psychoeducation alone did not improve the QoL for carers of PWD.[20] However, a recent systematic review and meta-analyses reveal that combining psychoeducation and other intervention components such as carer peer support group facilitated by trained health professionals showed effectiveness in improving carers' QoL.[21] Additionally, a systematic review and meta-analyses also confirm that multicomponent intervention programmes on carers show a large effect size on intervention outcomes compared with single-component intervention programmes.[22] However, most multicomponent intervention programmes for carers were delivered in a face-to-face manner and research evidence on online multicomponent interventions for carers that include the WHO iSupport programme is scant.

To optimise intervention effects for carers of PWD, we codesigned an online multicomponent intervention programme or the online tailored iSupport programme prior to the present study.[23] The programme comprised an iSupport facilitator-enabled: (1) online psychoeducation programme for carers using the web-based Chinese iSupport manual; (2) virtual carer peer support through monthly meetings and weekly interactions using WhatsApp or WeChat and (3) needs-based access to dementia care resources and care services via online or phone communication. We undertook a 9-month RCT to evaluate with 266 carers of PWD recruited from participating aged care and healthcare organisations from Australia and greater China, including Beijing, Xi'an, Taipei, Hong Kong and Macau.[23] The intervention lasted 6 months and we observed the outcomes from carers for an additional 3 months after the intervention. The results from the RCT indicate that the online tailored Chinese iSupport programme has a positive effect on carers' mental health-related QoL, self-efficacy in controlling upsetting thoughts and distress reactions to changed behaviours of PWD than the usual care group at 6 months postintervention.[23]

On the completion of the RCT, we undertook stakeholder consultations on how to embed the

tailored iSupport programme and the usual iSupport programme in routine care services in memory clinics and community health centres in China and in Chinese ethno-specific aged care organisations in Australia using a survey study. The usual iSupport programme is an online self-learning programme for carers using the iSupport manual only without receiving additional support from the iSupport facilitators. In total, 101 carers in Australia and 134 carers in Xi'an participated in the study.[4 10] The study identified that 90% of carer participants in Xi'an and 70% of carer participants in Australia were willing to use the Chinese iSupport manual. The most to least preferred formats of the iSupport manual were web-based (63%), audiobook (60%) and paper-based (30%) iSupport manual in Xi'an and audiobook (76%), web-based (65%) and paper-based (48%) iSupport manual in Australia. Furthermore, 89% of carer participants in Xi'an and 82% of carer participants in Australia would like to have an iSupport facilitator to deliver the tailored iSupport programme and 80% of carer participants in Xi'an and 72% of carer participants in Australia were willing to pay for the services delivered by the iSupport facilitator using either their own cost (in Xi'an) or means test-based aged care funding in Australia. The findings informed the project team of strategies to embed the usual iSupport innovation and the tailored iSupport innovation in routine care services in the present study.

Study aims

This RCT has two coprimary aims: (1) to determine the effectiveness of the 'usual support' and the 'tailored iSupport' innovations and (2) to evaluate the effectiveness of the strategies applied to embed the two innovations in the real-world setting.

The rationale for choosing those two innovations in this trial is to acknowledge that a proportion of carers do not want the 'tailored iSupport' delivered by the iSupport facilitator but would like to access the evidence-based Chinese iSupport manual in various formats.

METHODS AND ANALYSIS

Study design

A hybrid type II effectiveness-implementation RCT will be applied to address the aims of the study. This study design will enable the researchers to evaluate the effectiveness of the two iSupport innovations and the effectiveness of implementation strategies to embed the two innovations in routine care services in a single study. We will apply the Reach-Effectiveness-Adoption-Implementation-Maintenance (RE-AIM) framework to guide the hybrid study to achieve the study aims. The RE-AIM refers to (1) reach and representativeness, (2) effectiveness, (3) adoption, (4) implementation and (5) maintenance.[24] We outline the operational definition of the RE-AIM in the study context in table 1. To achieve the evaluation of the implementation strategies to embed the two iSupport innovations in routine care services, we will apply a nested qualitative study in the RCT described by Doyle *et al*.[25] The study protocol was peer-reviewed in a nationally competitive grant scheme, by the ethics committees in three universities and the Australia New Zealand Clinical Trials Registry.

Study settings

This study will be undertaken in (1) three Chinese ethno-specific aged care organisations in two states (NSW and SA) in Australia; (2) a hospital memory clinic and a geriatric ward in an affiliated hospital of Xi'an Jiaotong University located in the capital city of Shaanxi Province; and (3) an affiliated hospital memory clinic and an affiliated community health centre of Zunyi Medical University, Guizhou Province.

Table 1 The operational definition of the RE-AIM in the study context

Domains	Application to the study context and research questions/hypotheses
Reach	The carer participation rate considering carers who are willing to participate in iSupport innovation programmes among eligible carers.
Effectiveness	The impact of the two types of iSupport interventions on carers, people with dementia (PWD) and frontline staff.
Adoption	The units or departments that are willing to adopt the iSupport innovations among eligible units or departments in the participating organisations.
Implementation	The adherence to the study protocol by carers, frontline staff and facilitators; and the work environment adjustments made by participating organisations.
Maintenance (sustainability)	iSupport is maintained in real-world settings of aged care and healthcare organisations after the trial.

RE-AIM, Reach-Effectiveness-Adoption-Implementation-Maintenance.

Participants

Carer participants

The inclusion criteria for carers are aged 18 years or over; caring for an adult living with dementia at home at least two times a week. If a care recipient has no formal dementia diagnosis but meets cognitive impairment using the 'AD8 Dementia Screening Interview',[26] the carer will also be included in the study. The exclusion criteria are carers with self-reported severe mental health conditions or terminal illness. Participating organisations will help with the distribution of project information and posters to potential participants using their internal communication channel for example newsletters. Carers who are willing to participate in the trial will contact a site-specific researcher and discuss their consent to the project. The planned period for recruiting sufficient carers to the trial is between 22 May 2023 and 30 September 2024.

Staff participants

We will invite frontline staff who provide direct care services to carers of PWD to the study. We will exclude agency staff from the trial. We will use similar recruitment strategies described in recruiting carers for the staff. We will also invite staff in leadership and management positions to the study to discuss the maintenance and sustainability of the two iSupport innovations.

iSupport facilitators

The iSupport facilitators will be appointed by their organisations through an internal selection

process. They will be registered nurses or social care professionals with at least 2 years of experience in the care of PWD.

The tailored iSupport innovation

Carers in the 'tailored iSupport' group will be assigned to a trained iSupport facilitator. Carers will engage in the following activities delivered by the facilitator remotely for 6 months: (1) individualised learning: the facilitator will assess carers' individualised learning needs in the programme in an individual meeting lasting 45–60 min prior to the intervention using the 'Risk Appraisal Measure' we adapted from Czaja *et al*.[27] The facilitator will recommend learning modules, for example, 'Module 5 Dealing with changed behaviours' when the carer reports sudden/worrisome changes in the care recipient's memory and mood; (2) monthly peer support group: the meeting will include up to eight carers. The facilitator will use the standardised meeting agenda, which includes three items: your study progress using the iSupport manual, your experiences in applying knowledge, skills and attitudes to your own care activities, and your experiences in accessing resources and care services to address the care needs of your loved ones and yours. Each meeting will last about 45 min; (3) weekly text messages: the facilitator will also create carer support groups using WeChat or WhatsApp and send a short message extracted from the iSupport manual to enhance caregivers' understanding of dementia care. The facilitator will encourage carers in the same group to exchange messages to strengthen social support; (4) individualised assistance based on carers' requests. Carers are encouraged to make appointments with their facilitator to request assistance to access and use resources/services based on the care needs of their care recipients. For example, when their care recipients experience sudden changes in behaviours, the carer will contact the facilitator who will recommend a General Practitioner visit to identify the causes or refer them to Dementia Support Australia (in Australia's study sites only). Facilitators will maintain a portfolio to record all contact instances with carers throughout the intervention period. The intervention will last 6 months.

The usual iSupport innovation

Carers in the 'Usual iSupport' group will be guided by frontline staff either face-to-face or remotely in accessing iSupport manual in their preferred formats to perform self-directed learning. They can select the iSupport learning modules and units to perform self-paced learning to meet their learning needs using the web-based interactive learning, or the audiobook or the e-book. There would not be onboarding session, nor receiving support from the iSupport facilitator. After the 6-month trial, carers will be offered to access peer support group.

Outcome measures

We will measure outcomes for carers, their care recipients and participating organisations in the trial in relation to the effectiveness of the two iSupport innovations and the effectiveness of strategies applied to embed the two iSupport innovations in routine care services at baseline, 3 months and 6 months. Based on our previous study, it would take 20–40 hours for a carer to complete the interactive learning using the iSupport manual.[23] The reported follow-up time for carers in the usual iSupport programme was 3 months in previous studies.[18 19] Therefore, a 3-month outcome measure interval in this study is adequate. The RE-AIM framework informs the data collection plan to measure the outcomes as outlined in table 2 and detailed in the following sections.

Measures on iSupport innovation effectiveness

The measures are based on these hypotheses: carers receiving the 'Tailored iSupport' will report (1) a higher level of mental health-related QoL (primary hypothesis) at 6 months postinitiation of the intervention; (2) a higher level of physical health-related QoL; (3) a higher level of self-efficacy; (4) a higher level of QoL of PWD via a proxy rating; (5) fewer unplanned hospital admissions, fewer emergency department presentations and a lower rate of permanent admission to residential aged care of PWD and (6) better quality care experiences of PWD via proxy ratings, compared with those in the 'Usual iSupport group'. An RCT design will be applied to test these

Table 2 The RE-AIM framework informed outcome measures

Outcomes/relation to RE-AIM	Instruments used and quantitative and qualitative data collection
Carers	
QoL/effectiveness	12-Item Short-Form Health Survey (SF-12): The SF-12 includes 12 items measuring two domains: mental-health-related QoL and physical-health-related QoL. Higher scores indicate better QoL.
Self-efficacy/effectiveness	RIS Eldercare Self-Efficacy Scale: This test includes three subscales with 15 items: self-efficacy for obtaining respite, responding to atypical patient behaviours and controlling upsetting thoughts about caregiving. Higher scores indicate better self-efficacy.
Carers' experiences in the two iSupport innovations/ implementation	Record monthly peer support group meetings and interviews with carers.
People with dementia	
QoL/effectiveness	QoL in Alzheimer's Disease (QOL-AD)-Proxy: This test has 13 items. Higher scores indicate better QoL.
Unplanned hospital admissions, emergency department use or admission as a permanent resident to an aged care facility/effectiveness	Carers' self-reported survey 6 months prior to the intervention and during the 6 months intervention. The report will be validated by the research assistant.
Aged care organisations	
Carers receiving the 'tailored iSupport' will report better quality care experience of PWD via proxy ratings, compared with those in the 'Usual iSupport group'/effectiveness	Quality of care experience (QCE) for clients receiving community aged care-proxy rating. This QCE has six items. The higher score indicates the better quality of care experience.
Characteristics of clients with dementia and their carers/reach	The deidentified organisations' datasets and records.
Numbers of carers who are willing to participate in iSupport and their characteristics/reach	Baseline survey data.
Numbers of carers who completed iSupport/reach	Survey data at baseline, 3 months and 6 months.
Number of carers who withdrew and reasons/ implementation	Survey data at baseline, 3 months and 6 months; Facilitator records.
Frontline staff engaged in iSupport delivery to carers and support from iSupport facilitator will report positive experiences in the care of PWD and in working with their family carers/implementation.	We will conduct focus groups with frontline staff in each study site (8–10 in each group) at 3 months and 6 months, respectively, from the baseline to understand the experiences of frontline staff in the project.
Work environment adjustments needed to embed iSupport/implementation	Record in the 'Facilitator portfolio' submitted to the project team on a monthly basis; organisations' records.
Time spent by facilitator on carer peer support meeting/implementation	Facilitators' records
Time spent by facilitator on sending text messages to carers/implementation	Facilitators' records
Time spent by facilitator on assisting carers to access anduseg resources/implementation	Facilitators' records
Carer satisfaction with iSupport facilitator's support/ implementation	Project audit surveys with carers at 3 months and 6 months.
The experiences of facilitators in the project/implementation	Facilitator portfolio submitted to the project team and recorded online debrief sessions with peers and the project team.
The three industry partners have embedded the 'usual iSupport' and the 'tailored iSupport' in routine care services of new sites/adoption	Organisations' records. Interviews with iSupport facilitators, people in the management and leadership position of the participating organisation.
The facilitators have trained new facilitators to implement the 'usual iSupport' and the 'tailored iSupport' in new sites/adoption	Facilitators' records; organisations' records. Interviews with iSupport facilitators, people in the management and leadership position of the participating organisation.

Continued

Table 2 Continued

Outcomes/relation to RE-AIM	Instruments used and quantitative and qualitative data collection
iSupport is offered to carers after the trial/ maintenance	Organisations' records. Interviews with iSupport facilitators, people in the management and leadership position of the participating organisation.

QoL, quality of life; RE-AIM, Reach-Effectiveness-Adoption-Implementation-Maintenance.

hypotheses. The RCT design is shown in figure 1, Consolidated Standards of Reporting Trials flowchart and detailed in the following sections. The RCT follows the Standard Protocol Items: Recommendations for Interventional Trials checklist (see online supplemental file 1).[28] We have also developed the TIDieR checklist (see online supplemental file 2) to allow replication of the study.[29] All measurement tools used in this study were translated and validated in Chinese.

Mental health-related QoL and physical health-related QoL of carers

We will use the 12-Item Short-Form Health Survey (SF-12)[30] to measure mental health-related QoL and physical health-related QoL. The SF-12 includes six items measuring mental

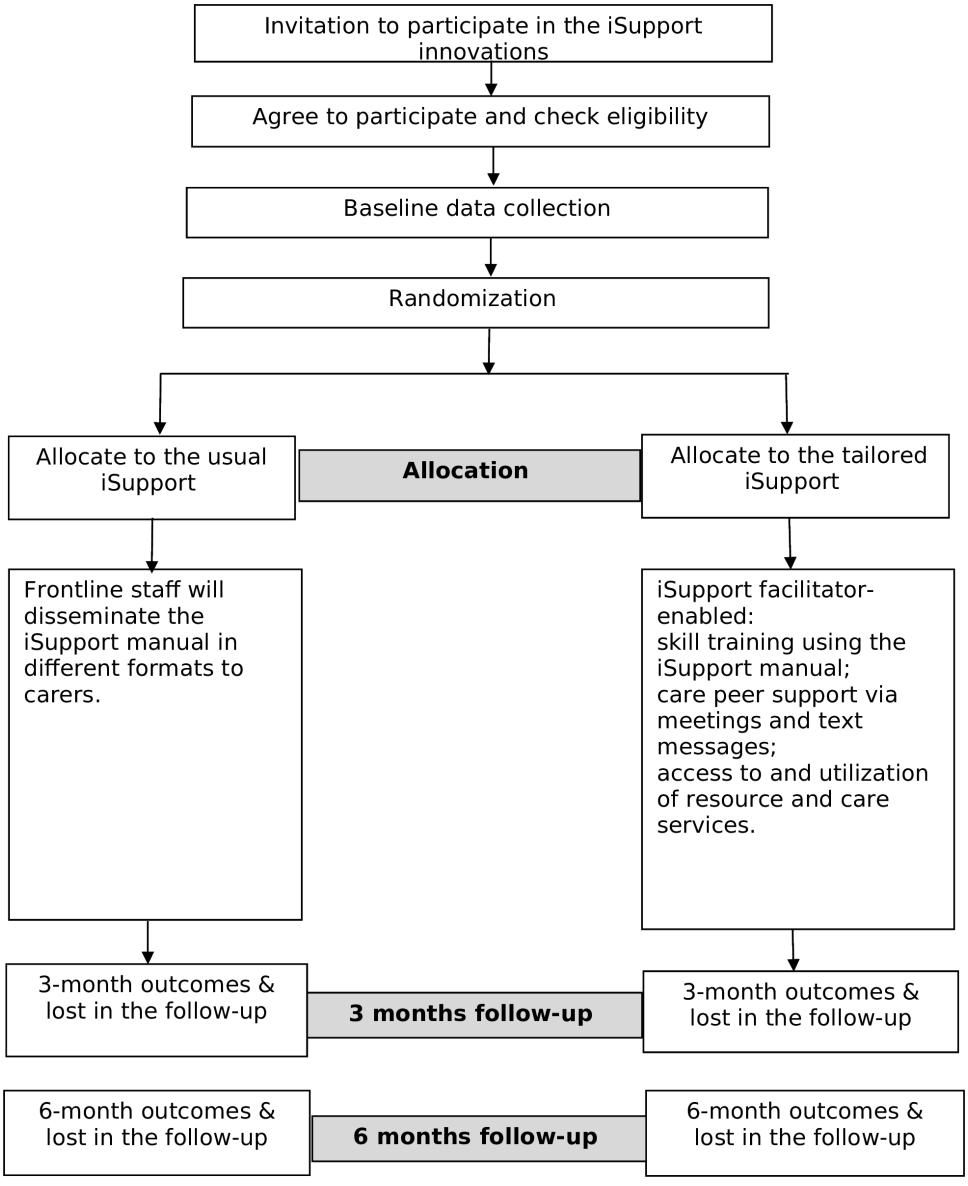

Figure 1 CONSORT flowchart. CONSORT, Consolidated Standards of Reporting Trials.

health-related QoL and physical health-related QoL, and higher scores indicate better QoL. The Chinese version shows an internal consistency of 0.78.[31]

Self-efficacy of carers

We will apply the Revised Scale for Caregiving Self-Efficacy[32] to measure self-efficacy. This tool includes three subscales with 15 items: self-efficacy for obtaining respite, responding to changed behaviours and controlling upsetting thoughts about caregiving. The Chinese version shows an internal consistency (Cronbach's α) of 0.89–0.91.[33] Higher scores indicate better self-efficacy.

QoL of PWD

We will use the QoL in Alzheimer's disease-Proxy to measure the QoL of PWD.[34] This tool has 13 items, and higher scores indicate better QoL. The Chinese version has an internal consistency of 0.87.[35]

Unplanned hospital admissions, emergency department presentations and permanent admission to nursing homes of PWD

We will analyse carers' self-reported survey 6 months prior to the intervention and during the 6-month intervention. The research assistant will validate the report.

Quality care experience of PWD

We will use the 'Quality of care experience (QCE) for clients receiving community aged care-proxy rating' to measure this outcome.[36] This QCE has six items. A higher score indicates a better QCE. The internal consistency is 0.74.

Measures on implementation strategies

iSupport innovations to reach carers

We will collect the characteristics of PWD and their carers from the deidentified organisations' datasets and records. We will use these data to compare the characteristics of PWD and their carers in the two iSupport innovations who complete the trial. Findings from this aspect will help the analysis of factors affecting the two iSupport innovations to reach carers of PWD.

Implementation

We will monitor the implementation process by analysing the number of carers who withdrew and reasons via survey at baseline, 3 months and 6 months and the records from the iSupport facilitators. We will explore carers' experiences in iSupport innovations via interviews, recorded carer group meetings and carers' satisfaction with iSupport facilitators via survey. We will also explore frontline staff's experiences in delivering 'the usual Support' to carers via focus groups or interviews. Moreover, we will analyse how iSupport facilitators make work environment adjustments to fit the two iSupport innovations with the real care situations by analysing the monthly iSupport Facilitator Portfolio. Furthermore, we will monitor the time that the iSupport facilitator spends on carer peer support meetings, sending text messages to carers and assisting carers in accessing and using aged care resources and services using the information from iSupport Facilitator Portfolios.

Adoption

We will collect data on how the participating organisations have embedded the 'Usual iSupport' and the 'Tailored iSupport' in routine care services of new sites via organisations' records submitted to the project team and interviews with iSupport facilitators, people in the management and leadership position of these organisations. Moreover, we will collect data on whether the iSupport facilitators have trained new facilitators to implement the 'Usual iSupport' and the 'Tailored iSupport' in new sites on the completion of the trial by interviewing the iSupport facilitators.

Maintenance

We will collect data on the participating organisation's initiative and funding allocated to maintain the two iSupport innovations after the trial via interviews with iSupport facilitators, people in the management and leadership position of the participating organisations.

Sample size calculation

The sample size calculation is based on the primary outcomes of the mental health components of the SF-12 for carers and is estimated based on an earlier RCT with similar intervention components for carers.[37] We used a moderate mean effect size of 0.57 to determine a sample size of 66 carers per group to achieve 90% power to detect a difference between means of 4.93 with a pooled SD of 8.63 (median effect size of 0.57) in a parallel randomised controlled design. Considering a 20% attrition rate in a 6-month RCT, we will recruit at least 158 carers to the trial.

Randomisation

Carers will be randomly assigned to receive either the 'Usual iSupport innovation' or the 'Tailored iSupport innovation' after baseline data collection (see figure 1). A block randomisation will be applied to assign carers to one of the two groups for each recruitment site to ensure the equivalent size and conditions of the two groups, for example, spouse carers versus non-spouse carers and PWD with similar stages of dementia in each treatment group. A researcher who has no knowledge about and contact the carers will assist the randomisation.

Data collection

The type of data and the approach to data collection are outlined in table 2. We will collect both quantitative and qualitative data to evaluate the effectiveness of implementation strategies. Data to assess the reach and representativeness of carers in the two iSupport innovations will be extracted from the organisation's database and the baseline survey data. Data to monitor

the project implementation will be collected via interviews with carers, focus groups with frontline staff engaged in delivering the usual iSupport innovation, routinely collected carer support group meetings and iSupport facilitator portfolios. Data to assess adoption and maintenance will be collected via interviews with iSupport facilitators and people in the management and leadership position.

We will collect quantitative data to measure the effectiveness of the two iSupport innovations on the QoL and self-efficacy of carers, carers' satisfaction in the trial and the QoL of PWD and unplanned hospital admissions, emergency department presentations and admission as a permanent resident to an aged care facility, and perceived quality of care of PWD via self-administered survey with carers at baseline, 3 months and 6 months. A site-specific researcher assistant will contact carer participants and offer either online survey via Qualtrics or hardcopy survey via preaddressed and prepaid mails based on participants' preferences. The research assistant will be available for carers to complete the survey if requested.

Data analysis

Audio-recorded carer peer support meetings, interviews and focus groups will be transcribed verbatim by site-specific researchers for data analysis and will be cross-checked by the site leaders. Transcripts will be entered into a computer-assisted qualitative data analysis programme, NVivo V.13, to assist coding management. Thematic analysis will be applied through coding, grouping codes and summarising codes into themes.[38] Site-specific researchers will perform the thematic analysis and the data analysis will be cross-checked by the site leader to ensure study rigour. Regular team meetings will be held to discuss the findings to reach a consensus on themes and subthemes.

Quantitative data will be analysed on an intention-to-treat basis based on group assignments. The missing values will be filled using multiple imputation. Data will be entered into IBM SPSS V.29 for data analysis. A biostatistician who will be blinded to group assignments will undertake data analysis. A multivariate mixed effect linear regression model will be applied to fit linear mixed models and to examine the primary and secondary outcomes between groups. As the outcome occurs for each individual with repeated time points, the mixed effect models will capture both fixed effects and random effects within the hierarchical structure of the data. The fixed effects, including group effect, time effect and group x time interaction, will be analogous to the regression coefficients. The random effects represent the estimated variability in the intercept to account for repeated measurements. The maximum likelihood estimate procedure will be used to compare significant differences in primary and secondary outcomes over time and between groups. The two-sided test will be performed for all analyses, and the level of significance will be set at $p<0.05$.

Project governance, data monitor and study fidelity

We will establish a steering committee to oversee the trial. Chief investigators and the representatives of participating organisations will serve as committee members and meet monthly to discuss the processes, outcomes, issues and adverse events identified and how to manage these. Flinders University is the lead organisation to manage the trial. A team member at Flinders University will be appointed as a coordinator to undertake regular auditing activities to ensure that the trial adheres to the study protocol, record any changes to the protocol, monitor recruitment, retention, data quality, record, report and work with the team to deal with adverse events. Any changes to the protocol will be made in public via the trial registry site.

We will train iSupport facilitators to standardise the delivery of the two iSupport innovations within their organisation. The training programme will include a written 'iSupport Facilitator Manual', which will include principles, guidelines, case scenarios and tools and resources for them to perform self-learning. The project team will provide three 2-hour training sessions prior to the trial, a 30 min fortnightly online debrief sessions during the 6-month intervention and needs-based coaching support provided by the project team. The training programme will enable them to develop leadership, knowledge and skills to work with carers of PWD and staff in their organisation to implement the two iSupport innovations and to train new facilitators to adopt the iSupport services in new sites. The facilitators will provide monthly staff training on iSupport using the existing paid staff development time and practical support for them in the workplace. The facilitators will train new facilitators in their organisation to adopt iSupport in new sites and sustain iSupport after the project life.

We will also train site-specific researchers to standardise data collection, maintain confidentiality of information, data entry by two persons, analyse data and report findings. We plan to provide a 2-hour training session prior to the trial and fortnight online meetings to discuss the recruitment, retention, data collection and data analysis for these researchers. The researchers will inform participants before they make decisions on their participation in the study that they will be free to withdraw at any time during the study. However, they will be unable to withdraw their deidentified data from this project. The data collected before their withdrawal (ie, recorded peer support meetings, focus groups and survey questionnaires) will be aggregated into the datasets for data analyses.

Ethics and dissemination

Ethics approval was obtained from Flinders University (project number: 5819), Xi'an Jiaotong University (project number: 2023–1629) and Zunyi Medical University (project number: KLL-2023–245). A site-specific researcher will discuss informed consent with participants and provide the following form based on participants' request: (1) providing a hardcopy consent form with prepaid preaddressed envelope; or (2) providing consent form via email to gain an electronic form; or (3) recording a verbal consent using a voice recorder. Each participant will be assigned a unique code number used in the trial to allow the reidentification while protecting their privacy during the data collection and data analysis. By the end of the project, each carer participant will receive AU$100 to appreciate their commitment to the trial. During the project life, deidentified data will be stored in the password-protected files of the computers used by the site-specific leaders and researchers. On the completion of the project, electronic data will be stored on the Flinders University research drive 5 years from the date of publication for governance and audit purposes. Deidentified data that support the findings of this trial are available by email request sent to the corresponding author on reasonable request.

The RE-AIM framework informs the project team of strategies to disseminate the two iSupport innovations as detailed in the following. The project team in China will adopt the 'Usual iSupport' in relevant wards and outpatient clinics in these participating hospitals and community care centres to enable carers of PWD to freely access and use the iSupport manual. Moreover, the two universities in China play a key role in their regions to provide continuing education programmes for health and social care professionals. They will incorporate the 'Usual iSupport' and the 'Tailored iSupport' innovations in the annual continuing education programmes. A playbook will be developed to enable health and aged care organisations to access resources and training programmes for iSupport facilitators to embed the 'Usual iSupport' in their routine care services. Furthermore, the project team will also train new iSupport facilitators to deliver the 'Tailored iSupport' innovation on the requests from health and aged care organisations. In addition, the project team will demonstrate their leadership to apply for the local and central government grants to lead further trials to scale up the 'tailored iSupport' innovation in community aged care organisations in China.

In Australia, the Carer Gateway is funded by the Department of Social Services, Australian Government and provides free services and support for carers from all groups and all care areas.[39] One of the Chinese ethno-specific aged care organisations in our project is a partner of a Carer Gateway provider in a state and has identified the Carer Gateway as a platform to integrate and sustain the 'Tailored iSupport' innovation. The project team in Australia will work with the three aged care organisations to partner with the Carer Gateway providers in their states and access funding to sustain the 'Tailored iSupport' innovation. The project team will also develop a playbook to enable other Chinese ethno-specific aged care organisations across states to access resources and training programmes for iSupport facilitators to scale up the 'Usual iSupport' innovation and the 'Tailored iSupport' innovation. The project team will also actively promote the 'Tailored iSupport' innovation via the 'Knowledge & Implementation Hub' at the Aged Care Research & Industry Innovation Australia, an Australian Government funded entity to disseminate evidence-based aged care innovations.[40] The project team will promote the two iSupport innovations via regular webinars organised by the Multicultural Aged Care, an organisation funded by the Australian Government via the 'Partners in Culturally Appropriate Care' scheme.[41] Furthermore, the project team will also train new iSupport facilitators to deliver the 'Tailored iSupport' innovation on the requests from aged care organisations.

Trial status

Recruitment started in May 2023 and will end in September 2024. The trial will end 6 months after the last inclusion, in March 2025.

Patient and public involvement

This study is part of a large study including two phases. In phase 1, the project team consulted with 10 advisory group members who are carers of PWD, care workers/health professionals in each study site (Australia, Xi'an and Zunyi) regarding the study protocol using focus groups. Findings enabled the team to confirm or revise the implementation strategies. For example, participants suggested the inclusion of carers of people without formal dementia diagnosis to reach carers to participate in the iSupport programmes as the dementia diagnosis rate was low based on their experiences. Moreover, participants suggested that frontline staff who had a close relationship with PWD were in an ideal position to deliver the 'usual iSupport' innovation to their carers. Therefore, we decided to prepare frontline staff, rather than the iSupport facilitator to deliver the 'usual iSupport' innovation. We will continue to work with the advisory group members during the RCT via quarterly meetings to discuss the processes and outcomes of the study and gain their advice on strategies to (1) reach carers to invite them to participate in the two iSupport innovations, (2) engage frontline staff in these two innovations and (3) sustain the two iSupport innovations after the trial.

Author affiliations
[1]Flinders University College of Nursing and Health Sciences, Bedford Park, South Australia, Australia
[2]Australian Nursing Home Foundation Limited, Sydney, New South Wales, Australia
[3]Chinese Australian Services Society, Sydney, New South Wales, Australia
[4]Chinese Welfare Services of SA Inc, Adelaide, Cosmopolitan Coastal, Australia
[5]Flinders University, Adelaide, Cosmopolitan Coastal, Australia
[6]College of Medicine and Public health, Flinders University College of Medicine and Public Health, Adelaide, South Australia, Australia
[7]Xi'an Jiaotong University, Xi'an, China
[8]Department of Critical Care Medicine, Affiliated Hospital of Zunyi Medical University, Zunyi, Guizhou, China
[9]Xi'an Jiaotong University, Xi'an, Shaanxi, China
[10]School of Nursing, Zunyi Medical University, Zunyi, Guizhou, China

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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ORCID iDs
Lily Dongxia Xiao http://orcid.org/0000-0002-4631-2443
Ying Yu http://orcid.org/0000-0001-8110-1038
Rujun Hu http://orcid.org/0000-0001-7654-2517

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