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Evaluating the effects of the World Health Organization's online intervention 'iSupport' to reduce depression and distress in dementia carers: a multi-centre six-month randomised controlled trial in the UK

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Summary

Background Sustaining the capabilities of dementia carers is a global priority. 'iSupport' is a self-guided online intervention designed by the World Health Organization (WHO) to reduce mental health problems in dementia carers. iSupport is undergoing global implementation, however there is an absence of effectiveness evidence. This study tested the effectiveness of iSupport to reduce distress and depression in dementia carers.

Methods A pragmatic randomised controlled trial was conducted in three centres. Adult carers (18+) living in the community were recruited in England, Wales and Scotland and randomly assigned (1:1) through a web-based system to iSupport or usual care. Outcome assessors were masked to allocation. The primary outcomes assessed the difference in distress and depression between baseline and six-months. The target sample size was 350 to enable 90% power, significance at 2.5% including 25% attrition (262 completers) on either outcome. Analysis followed the intention-to-treat (ITT) principle. The trial was registered with ISRCTN registry (17420703).

Findings Between 12th November 2021 and 31st March 2023,177 carers (50.3%) were randomised to usual care and 175 (49.7%) to iSupport. 263 (74.7%) completed the trial. All were included in the ITT analysis. Mean distress scores at six-months were 20.0 (SD = 8.3) for usual care and 20.6 (SD = 8.6) for iSupport. The mean difference was 0.16 (95% CI −1.17 to 1.49, p = 0.29) after adjusting for covariates. Mean depression scores at six-months were 9.5 (SD = 7.0) for usual care and 9.8 (SD = 6.5) for iSupport. The mean difference at six-months was −0.54 (95% CI = −1.70 to 0.62, p = 0.44). No serious adverse events were linked to the trial.

Interpretation To our knowledge this is the largest trial evaluating a self-guided online intervention in UK dementia carers, and the first to successfully evaluate the effectiveness of iSupport. The null findings are significant given the ongoing global implementation of iSupport by the WHO and the adoption of self-guided interventions into mainstream care delivery as part of digital health transformations.

Funding NIHR.

Keywords: Dementia; Informal carers; Family carers; Randomised controlled trial; Self-guided interventions; Online interventions; E-Health; Digital health

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Research in context

Evidence before this study

Most people living with dementia are cared for at home by a family member. These carers can experience significant mental and physical ill-health as a consequence of their role. Sustaining the capabilities of dementia carers is a global priority and the provision of carer education and training is reinforced by national and international policies. Self-guided digital interventions are a low-cost option for delivering education and support, with the potential to reach a large number of carers. The World Health Organization developed 'iSupport for dementia carers', an online resource based on the principles of cognitive behavioural therapy, relaxation strategies and psychoeducation, which is undergoing global implementation.

An umbrella review of systematic reviews of web-based interventions for dementia carers was conducted alongside this study. This aimed to identify the types of web-based interventions that have been developed for carers of persons with dementia in the community, and suggest which types are most effective. The search for systematic reviews was undertaken in PsycINFO, Web of Science, CINAHL, MEDLINE, Cochrane Library, and PubMed, using keywords "informal care*" OR "family care*" OR "dementia care*" AND "internet" OR "online" OR "technology" AND "dementia" OR "major neurocognitive disorder" OR "Alzheimer*". The reference lists of review papers were also manually searched, and experts were consulted regarding review titles. 106 titles and abstracts were screened and 21 reviews were included in the final synthesis, which were of variable quality. Many of the papers included in each review were of low quality. Findings suggest that online interventions were most effective when they included psychoeducation, psychosocial, and psychotherapeutic elements, however this must be interpreted with caution due to study quality limitations, indicating the need for more robust research and randomised trials of a high quality.

Prior to study commencement, we also searched PubMed from inception to March 31st 2020 for original research, protocols or systematic/scoping reviews to ascertain whether our intervention of interest—'iSupport for dementia carers'—was effective. We used the search terms "iSupport" AND "caregivers" OR "carers" AND "dementia". The search returned three relevant articles; protocols for RCTs of iSupport in India and in the Netherlands and a pilot RCT in Portugal, confirming the absence of clinical and cost effectiveness evidence and the need for this study.

Added value of this study

This is the first robust RCT to test the effectiveness of iSupport for dementia carers, conducted in three countries within the UK. We successfully recruited carers who self-identified as experiencing distress, depression or anxiety reflecting the 'real world' use of self-guided interventions as part of a public health approach to prevention. Our participant retention through the trial was good, as was the data completeness. However, we found no evidence for the effectiveness of iSupport compared to usual care for the two primary outcomes (depression and distress) or the secondary outcomes (resilience, dementia knowledge, quality of the care relationship, anxiety). Sensitivity analysis found longer time spent using iSupport was predictive of lower ratings of quality of life of the person with dementia by the carer. No adverse events were attributed to the study.

Implications of all the available evidence

This was a robust trial managed and governed through the standard operating procedures of a specialist clinical trials unit, which does not support the effectiveness of iSupport for dementia carers in relation to intention-to-treat analysis of primary and secondary outcomes. To our knowledge this is the largest RCT evaluating a self-guided online intervention compared to usual care in UK dementia carers, and the first RCT globally to successfully evaluate the effectiveness of iSupport. The null findings contrast other studies of technology-based interventions, however the existing evidence is predominantly low quality. The null effects may have been due to low engagement with iSupport over the intervention period, highlighting the limitations of self-guided digital interventions in health and care delivery without any additional therapeutic support. In its current format iSupport is unlikely to be effective as a self-guided intervention, especially in countries where carers have access to a range of services and information. Future research should consider testing the effectiveness of iSupport alongside human contact for psychosocial support and guidance.

Introduction

Dementia is one of the primary sources of disability, care dependency and death globally.[1] The number of people living with dementia globally is expected to rise from 46.8 million in 2015 to approximately 131.5 million by 2050,[2] necessitating dementia as an international public health priority.[3] There is no cure, medical treatments are limited, and most people with dementia are cared for at home by a family member or friend who has little knowledge of the condition and how to best manage it. These carers, often termed 'informal carers', are unpaid, regularly performing care tasks similar to those carried out by paid health or social service providers alongside employment and family life.

The detrimental physical and mental consequences of caring are well recognised.[4–6] However, informal care benefits society, with their work contributing over $322

billion of the $818 billion cost of dementia globally.[7] Sustaining the health and capabilities of dementia carers is of global importance and the global action plan on the public health response to dementia prioritises supporting carers, calling for the provision of accessible evidence-based information to improve knowledge and skills and prevent stress and health problems.[3] This is further emphasised in UK national dementia strategies and clinical guidelines.[8] Therefore, access to appropriate, useful, low-cost, effective information is a global and national priority for supporting informal carers.

Online interventions are an often-proposed way to address this, given the increasing costs of dementia care. Internet-delivered carer interventions, especially self-guided interventions, are appealing to service providers due to low-costs and potential scalability/reach, and to carers who can access them when they wish, from a place convenient to them, working at their own pace. Technology-mediated interventions (web-based which can include self-guided, support forums, and facilitator support) are beneficial in supporting informal carers of people with dementia.[9] However, the evidence is tentative when specifically considering the benefits of self-guided interventions in reducing the stress and distress of dementia carers due to the varying quality of the research and the absence of high quality RCTs.[10]

Given the pressing need to prioritise supporting dementia carers around the world, the World Health Organization (WHO) developed 'iSupport', an evidence-informed self-guided intervention designed for online delivery to help dementia carers provide good care and take care of themselves. Roll out of this intervention has already begun globally, with over 40 countries in various stages of translation and cultural adaptation of the content. However, despite the global roll out and interest from national care providers, evidence of effectiveness is absent. There were only two iSupport RCT protocols published ahead of commencing this study[11,12] with no published evidence of clinical and economic effectiveness.[13] A pilot RCT in Portugal[14] recruited only 42 of the 184 participants specified in the protocol and the results are inconclusive.[15] Given this global rollout and lack of effectiveness data there was a critical need to understand whether iSupport is effective in reducing carer distress and depression.

To address this, we conducted the first robust and pragmatic multi-centre randomised controlled trial (RCT) in the UK to test the clinical effectiveness and impact on health-related quality of life of iSupport to reduce distress and depression in dementia carers. The findings of this study are of particular importance given the ongoing global implementation of iSupport by the WHO. It is also, to our knowledge the largest RCT evaluating any self-guided online intervention compared to usual care in UK-based dementia carers.

Methods

A multi-centre, single blind RCT assessed the effectiveness of iSupport on reducing distress and depression in dementia carers living in the community in England, Wales and Scotland. A nested internal pilot study monitored progression criteria over the first six months of recruitment.

- Recruitment and set up/training of sites within time allocated: Go: 3, Review: 2, Stop: 1.
- Recruitment of participants based on target of n = 110 by month 6 of recruitment: Go: ≥ 94 (≥ 85%), Review:55–93 (50–84%), Stop:<55 (<50%).
- Retention of recruited participants to 6 months, assessed as a percentage of those who should have reached 6 months at the time of internal pilot assessment: Go: ≥ 75%, Review:40–74%, Stop:<40%.
- Acceptability of intervention: assessed by utilisation of 'iSupport' (the number of participants who have logged in and used the system more than once): Go: ≥ 70%, Review:50–69%, Stop:<50%.
- Ability to collect outcome data (assessed on baseline and first follow-ups only). A measure would be a candidate for removal if less than 85% of participants attempt to complete a measure: Go: ≥ 85%, Review:70–84%, Stop:<70%. This only becomes a trial termination criteria if this were in relation to the primary outcome.

Ethical approval was granted by Bangor University's School of Health and Medical Sciences Academic Ethics Committee (reference: 2021-16915) and the Health Research Authority (IRAS project number: 311,565) via the London—City & East Research Ethics Committee (reference 22/LO/0688). The trial was overseen by a UKCRC registered clinical trials unit (CTU), a trial management group, an independent trial steering committee and data monitoring committee. The protocol is published[16] and the trial registered with the ISRCTN registry (17420703).

Participants

Adults aged 18+ were recruited who self-identified as an unpaid carer for at least six months of a person with a confirmed dementia diagnosis not living in a care facility, and who self-reported they experienced some stress, depression or anxiety. The study was advertised by the study partners (Alzheimer Scotland and Carers Trust Wales), the UK Join Dementia Research (JDR) register, two NHS health boards and through social media.

Potential participants who expressed an interest in the study were sent an information sheet and, if interested, screened for eligibility using a checklist corresponding with the inclusion/exclusion criteria through interviews over the phone or secure online video conferencing software by trained research assistants

from each of the centres (UCL, England; University of Strathclyde, Scotland; Bangor University, Wales). Participants were excluded if they reported receiving psychological treatment from a mental health specialist at the time of recruitment, were unable to comprehend written English, had no access to the internet, were unable to give informed consent to the trial, or had previously used 'iSupport' materials in the last twelve months. Reasons why potential participants declined or were not eligible to take part were recorded and if the individual agreed, their age, sex and ethnicity were also recorded and anonymised. Participants who declined or were not eligible were offered a list of support services organisations and a PDF version of iSupport. Informed consent was obtained at the baseline, recorded by email and saved as a PDF file in a secure folder. If the participant agreed the baseline assessment was conducted or a second meeting was arranged for the baseline assessment.

Randomisation and masking

Participants were randomly assigned in a 1:1 ratio to the iSupport intervention group or a usual care group. Stratification variables were site, along with age (18–40, 41–50, 51–60, 61–70, 71–80, 81+) and gender, which have been previously found to influence the outcome measure of caregiver distress.[17] Randomisation was undertaken by the research assistant inputting Participant ID and stratification variables into the CTU web-based system, which used a dynamic adaptive allocation algorithm[18] to ensure a good balance to the allocation ratio of 1:1, overall and within stratification variable. The researcher was masked to the randomisation allocation. The result of the randomisation and study instructions were sent to the participant by the trial manager. With the exception of the trial manager, chief investigator and participant technical support ('e-coach'), all the research team were masked to group allocation for the data collection and analysis period. Study participants were unmasked to group allocation asthe intervention required participants to actively commit to using the iSupport platform, which had to be explained ahead of consent so they fully understood the study requirements. After completing follow-up interviews, the research assistants recorded whether they thought they had been unblinded during the interview.

Procedures

"iSupport is an interactive, internet-based psychoeducation, skills and self-care intervention developed by the WHO. It can be accessed through a personal computer, tablet or mobile phone. The theoretical underpinnings of 'iSupport' are based on person-centred care, psychoeducation, relaxation, behavioural activation, cognitive reframing and problem solving. iSupport consists of five modules and 23 accompanying exercises (Fig. 1). Exercises take approximately 5–15 min each and follow the same format: information about a topic presented, short interactive exercises alongside case scenarios and questions with instant feedback on responses, a summary of the lesson and a relaxation exercise. iSupport is expected to improve carer skills, capability and understanding of dementia, wellbeing and prevent mental health problems. Reflecting the intentions of the intervention, the outcome measures assessed reductions in psychological morbidity, the promotion of personal capabilities to mitigate against morbidity, improvements in dementia knowledge and the patient-carer relationship. The version of iSupport in this study added verbal/audio introductions to modules along with information on support services specific to the UK. It is described in detail elsewhere.16" A non-exclusive licence for use was granted by the WHO and it was hosted securely on the website of the Pan American Health Organization. To reflect the 'real world' aspect of online self-help resource use, no 'dose' was specified but participants were provided access for six months and advised to use iSupport regularly to obtain the most benefit.

The usual care group were sent a booklet about being a dementia carer, either as a hard copy or PDF and were provided access to the WHO version of iSupport at the end of the study.

Data for the RCT were collected over the phone or through secure online video conferencing software by trained research assistants from each of the centres at three time-points. Baseline (T0; before randomisation) included the outcome measures and demographic information; three-months post-baseline (T1 follow-up) included the outcome measures; six-months post-baseline (T2 follow-up) included the outcome measures and (for the intervention participants) an assessment of system usability. Data were entered into MACRO, a secure clinical trials management programme.

Intervention group participants were sent a pseudo-anonymised username, hyperlink URL to iSupport and a short guide with instructions on how to logon. The e-coach contacted the participants shortly after randomisation to offer technical support, emailing again one-month post-randomisation, and once more for participants who had not used the intervention by two months. Following the internal pilot study, further contact by the e-coach at two months was made with participants who had only logged in once, and/or viewed the very first pages of a single module. All participants received a £20 gift voucher for taking part in the study.

Outcomes

All outcome measures were selected as valid and reliable indicators that theoretically relate to the intentions of the intervention. The two primary outcomes had evidence suggested from umbrella reviews[19] and meta-analysis[20] for the effects of technology-mediated interventions on reducing depression and distress. Consequently,

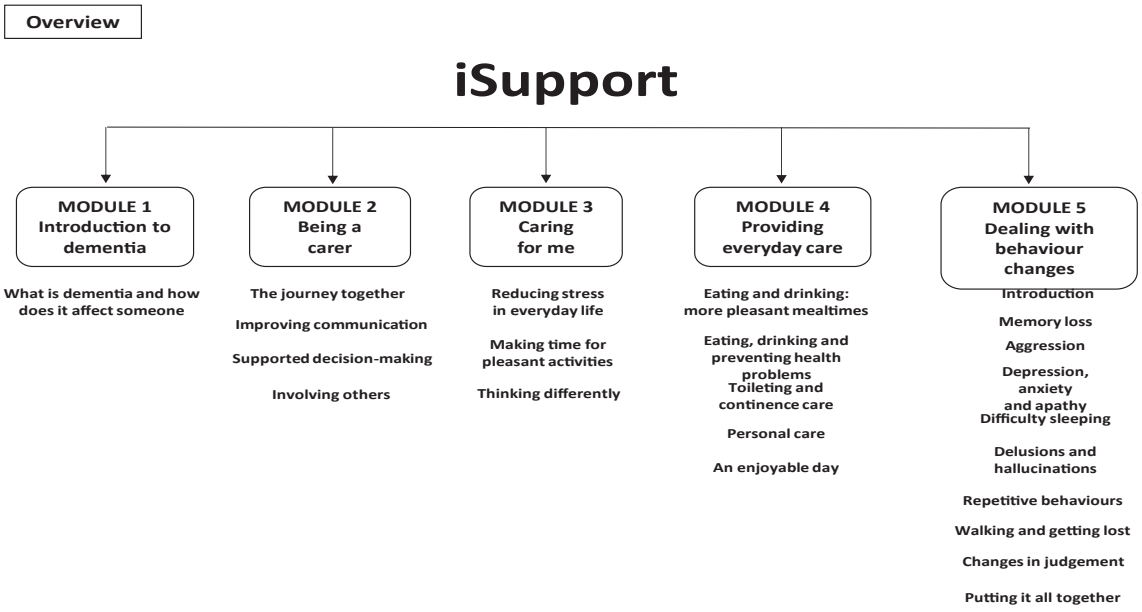

Fig. 1: The content of iSupport for dementia carers.

reductions in distress were measured by the 12-item Zarit Burden Interview, ZBI-12.[21] Item responses range from 0 (never) to 4 (almost always), scores of 0–10 = no to mild burden, 10–20 = mild to moderate burden and >20 = high burden. The ZBI-12 is considered valid for evaluation of burden in clinical practice and research as a fast, efficient option for screening burden among older caregivers of community-dwelling older adults.[22] Depression was measured by the 10-item Centre for Epidemiological Studies of Depression Scale, CES-D-10. Item responses range from 0 (rarely or none of the time present) to 3 (most or all of the time present). Scores ≥10 are indicative of clinically relevant depression.[23] CES-D is a valid and reliable scale for detecting dementia carer depression. It has added utility, beyond that of a caregiver burden scale, in identifying a subgroup of caregivers with depression but not burden.[24]

Secondary outcomes collected the frequency of common symptoms of anxiety, assessed through the Generalised Anxiety Disorder Questionnaire (GAD-7). Scores of ≥15 indicate severe anxiety.[25] Improvements in the way carers perceive they can manage their situation was assessed through the Resilience Scale-14 (RS-14). Scores of 14–56 = very low; 57–64 = low; 65–73 = on the low end; 74–81 = moderate; 82–90 = moderately high; 91–98 = high.[26] The influence of iSupport on the quality of the caregiving relationship was assessed through the 14-item Quality of the Carer-Patient Relationship (QCPR). Higher scores indicate better relationship quality and a score >42 indicates a 'good' relationship.[27] Improvements in how the carer understands their relative were assessed through the 25-item Dementia Knowledge Assessment Scale (DKAS).[28] The total score ranges from 0 to 50, with higher scores indicating better knowledge. The impact on the health-related quality of life of the person being cared for was assessed through the DEMQOL-Proxy, a 31-item instrument for measuring the health-related quality of life of people living with dementia, completed by the carer. Higher scores indicate a better quality of life.[29]

Intervention group data from the online platform recorded the number of times participants logged in and length of time using iSupport. Process evaluation data were also obtained but the full analyses are not included in this paper and will be reported elsewhere. Adverse event data were collected and reported following the CTU standard operating procedure for safety monitoring. This included information on whether the adverse event was linked to study participation. An independent data monitoring committee oversaw trial safety.

Statistical analysis

The sample size was estimated for the ZBI-12 and CES-D-10 as multiple primary outcomes. The multiple primary endpoint estimator in the R package with power of 90% and significance set to 2.5% established a sample of 262 would be required to have the potential to detect a standardised effect in at least one of these outcomes (0.4 for ZBI and 0.2 for CES-D-10) (Appendix pp 1–2). The attrition rate was based on nine dementia intervention studies (Appendix pp 3–4), where the mean attrition rate was 15.33% (range 2%–24%). N = 350 participants were

needed to accommodate a 25% attrition rate by six-months.

Data were extracted from MACRO using SPSS version 27, and then loaded into Stata version 16 for analysis. All data analyses were prespecified in a formal statistical analysis plan before completion of data collection while the statistician was masked to group allocation which was approved by the trial independent data monitoring committee (Appendix pp 5–19). Missing data and imputation were handled following the process defined in the statistical analysis plan (Appendix pp 11–12). Ahead of the analysis the assumptions of the analysis model were checked. Demographic characteristics were described using summary statistics. Primary and secondary outcomes were analysed on an intention-to-treat (ITT) basis which included all participants for whom data were available and analysed according to the group randomisation (iSupport vs usual care). The primary assessment for effectiveness was the adjusted estimates of the ZBI-12 and CES-D-10 scores between the two groups assessed at three-months and six-months (the primary time-point).

All outcomes were analysed using multi-level mixed effects linear models with baseline outcomes and age as covariates, gender (male, female, other, no answer), as a factor and site (Wales, England, Scotland) included as a random effect to account for the variance among the values at the different sites. The allocated group, time (baseline, three-month follow up, six-month follow up) and a time*group interaction were included. Effect sizes were estimated using adjusted mean differences from the model, standard errors and 95% confidence intervals. To account for multiple testing, two-sided p values less than 0.025 indicated significance for the primary outcomes (ZBI-12 and CES-D-10) and two-sided p-values less than 0.05 indicated significance for each secondary outcome.

The analyses were initially masked to group allocation with unmasking following all analyses. Following unmasking, sensitivity analysis to include intervention data for each outcome were conducted. The multi-level mixed-effects linear models were repeated and included the number of times logged in to iSupport and length of time spent using iSupport (in minutes) as covariates. For the usual care arm, the length of time spent using iSupport, and the number of logons, were both specified to be 0.

Role of the funding source

The funder of the study had no role in study design, collection, analysis and interpretation of data, in the writing of the report or in the decision to submit for publication.

Results

Between 12th November 2021 and 31st March 2023 we invited 2332 carers to take part in the study and 360 (15.4%) provided consent. Shortly after consent was provided, eight participants did not respond to further invitations to complete baseline assessment, leaving 177 (50.3%) randomised to the usual care group and 175 (49.7%) to the intervention group. Of these 263 (74.7%) completed the trial, including 137 (77.4%) in the usual care group and 126 (72.0%) in the intervention group. 1972 (84.6%) did not consent, mainly due to no response (see Fig. 2). Of the 596 screened volunteers who explicitly either declined or were not eligible, 282 agreed for some basic demographics to be recorded. Mean age (if given) 60.7 (SD 12.3; range 19–90); Ethnicity (if given) 93.6% White British, 6.4% in total for all other ethnic backgrounds. Sex (if given) 80.4% Female, 19.6% Male. These demographic characteristics are consistent with the consented population of participants (Table 1). All 352 participants were included in the intention-to-treat analysis.

The internal pilot assessed progression criteria six months after commencing recruitment. All sites were set up and trained in the time allocated (Go), 107 participants had been recruited and randomised (Go), 90.7% of participants remained in the trial (Go), 85% had attempted to complete each outcome measure (Go), 69.1% of iSupport group participants had logged in and used the system more than once (Review), leading to the e-coach requirements for contacting people at 2-months being changed from only contacting participants if they had not logged on at all to contacting them if they only logged in once, and/or viewed the very first pages of a single module.

The two groups were well balanced in terms of their baseline demographic characteristics. There were more females (n = 140; 79.1%) than males. Most (n = 328; 93.1%) described themselves as white English/Welsh/Scottish/Northern Irish/British, with English being the main language (n = 347; 98.6%). 152 (43.2%) described themselves as the spouse/partner of the person with dementia and 117 (50.3%) asthe child. The mean age was 62.2 (SD = 11.6) (Table 1).

93.5% (n = 329) of the participants reported caring for more than a year, with 159 (90.9%) in the intervention group and 169 (96%) in the usual care group. The median length of time spent caring was 3 years (IQR 2–5). 55.2% (n = 194) had a degree level education or higher. The median number of times the participants logged onto the iSupport platform was 4 (IQR 1–10). 46 participants (26.3%) logged on once, and one participant logged on 103 times. The median length of time spent using iSupport was 49 min (IQR 5–104). 32 of the participants (18.3%) spent 0 min using iSupport, and one participant spent 429 min using iSupport.

There were nine Serious Adverse Events (SAEs), three in the usual care group and six in the intervention group. Seven were not related to participation in the trial and two were unlikely to be related. There were three adverse events (AEs), one in the usual care group and

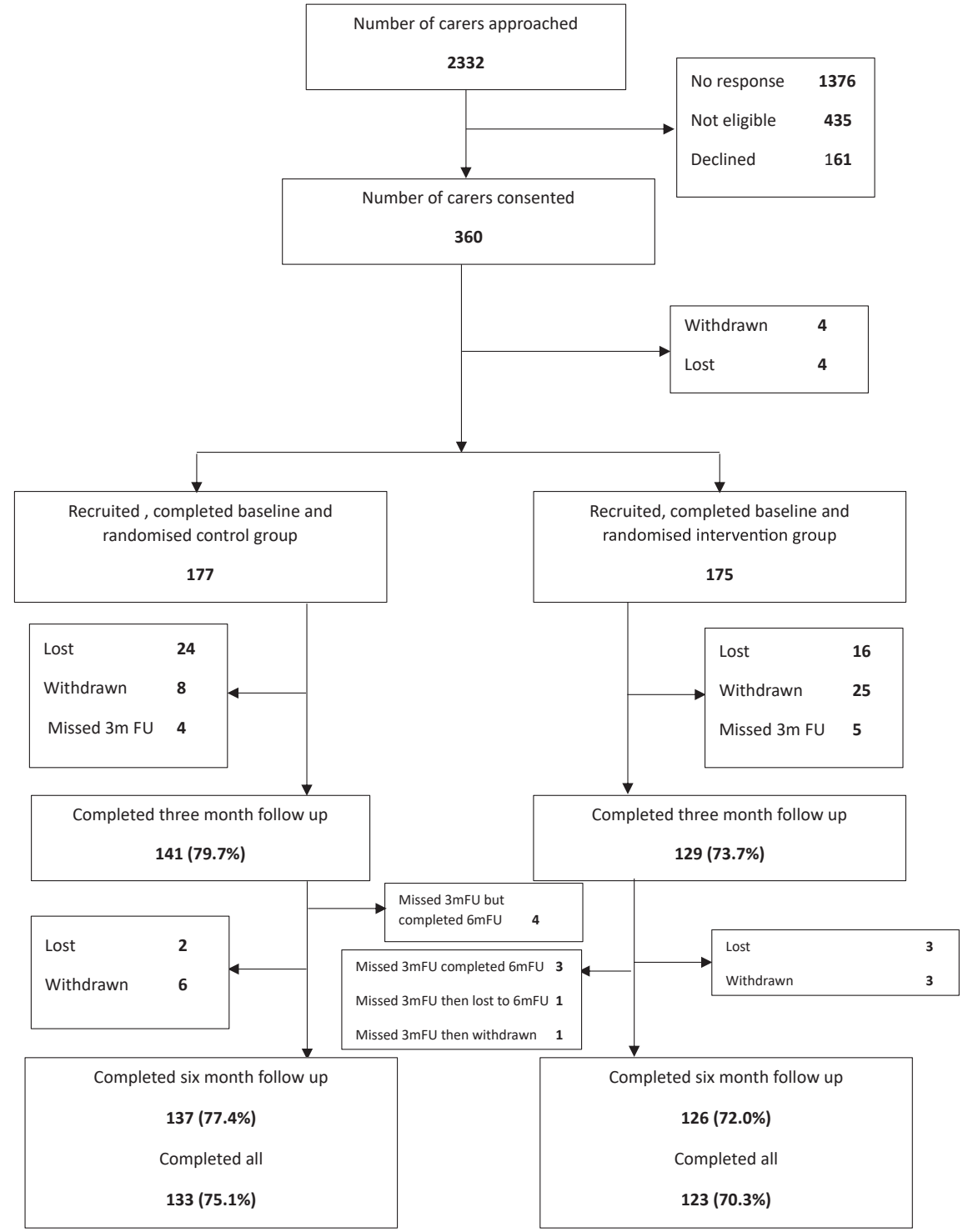

Fig. 2: CONSORT diagram for iSupport.

	Total (n = 352)	Usual care (n = 177)	iSupport (n = 175)
Age (years)			
Mean (SD)	62.2 (11.6)	61.9 (11.3)	62.6 (12.0)
Gender			
Male	71 (20.2%)	36 (20.3%)	35 (20.0%)
Female	280 (79.6%)	140 (79.1%)	140 (80.0%)
Other	0 (0%)	0 (0%)	0 (0%)
No answer	1 (0.3%)	1 (0.6%)	0 (0%)
Main language			
English	347 (98.6%)	175 (98.9%)	172 (98.3%)
Welsh	2 (0.6%)	0 (0%)	2 (1.1%)
Gaelic	0 (0%)	0 (0%)	0 (0%)
Other	3 (0.9%)	2 (1.1%)	1 (0.6%)
Ethnicity			
White English/Welsh/Scottish/Northern Irish/British	328 (93.2%)	164 (92.7%)	164 (93.7%)
Irish	1 (0.3%)	0 (0%)	1 (0.6%)
Any other White background	7 (2.0%)	4 (2.3%)	3 (1.7%)
Indian	3 (0.9%)	2 (1.1%)	1 (0.6%)
Chinese	1 (0.3%)	1 (0.6%)	0 (0%)
Any other Asian background	1 (0.3%)	0 (0%)	1 (0.6%)
White and Asian	2 (0.6%)	2 (1.1%)	0 (0%)
Any other Mixed/multiple ethnic background	2 (0.6%)	2 (1.1%)	0 (0%)
Caribbean	4 (1.1%)	1 (0.6%)	3 (1.7%)
Any other Black/African/Caribbean background	1 (0.3%)	0 (0%)	1 (0.6%)
Any other ethnic group	1 (0.3%)	0 (0%)	1 (0.6%)
Prefer not to say	1 (0.3%)	1 (0.6%)	0 (0%)
Level of education			
University Higher Degree (MA; MSc; PhD)	86 (24.4%)	47 (26.6%)	39 (22.3%)
First degree level qualification (BA; BSc)	108 (30.7%)	46 (26.0%)	62 (35.4%)
Apprenticeship	4 (1.1%)	0 (0%)	4 (2.3%)
HND; HNC; NVQ Level 4; teaching; nursing	48 (13.6%)	27 (15.3%)	21 (12.0%)
AS, A Level, Baccalaureate	27 (7.7%)	14 (7.9%)	13 (7.4%)
NVQ level 3 or below, BTEC, City and Guilds Craft	8 (2.3%)	2 (1.1%)	6 (3.4%)
Any other qualification	28 (8.0%)	17 (9.6%)	11 (6.3%)
None of the above	5 (1.4%)	3 (1.7%)	2 (1.1%)
Type of dementia (person cared for)			
Alzheimer's disease	160 (45.5%)	80 (45.2%)	80 (45.7%)
Vascular Dementia	54 (15.3%)	26 (14.7%)	28 (16.0%)
Familial Alzheimer's Disease	1 (0.3%)	0 (0%)	1 (0.6%)
Fronto-temporal Dementia	9 (2.6%)	5 (2.8%)	4 (2.3%)
Primary Progressive Aphasia	1 (0.3%)	1 (0.6%)	0 (0%)
Posterior Cortical Atrophy	2 (0.6%)	1 (0.6%)	1 (0.6%)
Dementia with Lewy Bodies	9 (2.6%)	4 (2.3%)	5 (2.9%)
Other	93 (26.4%)	47 (26.6%)	46 (26.3%)
Don't know	23 (6.5%)	13 (7.3%)	10 (5.7%)
Relationship to person with dementia			
Spouse/partner	152 (43.2%)	75 (42.4%)	77 (44.0%)
Sibling	5 (1.4%)	3 (1.7%)	2 (1.1%)
Child	177 (50.3%)	90 (50.9%)	87 (49.7%)
Parent	0 (0%)	0 (0%)	0 (0%)
Friend	3 (0.9%)	2 (1.1%)	1 (0.6%)
Other	15 (4.3%)	7 (4.0%)	8 (4.6%)

Table 1: **Baseline demographic data.**

two in the intervention group. Two were not related to participation in the trial and one was unlikely to be related. All events were unexpected and were reported according to the Protocol and CTU standard operating procedures.

The baseline ZBI score for both groups was >20 indicating high levels of distress, which was sustained at three-months and six-months for both groups. The mean baseline CES-D score indicated clinically relevant depression for the intervention group (m = 10.9), which was sustained at three-months but not six-months. The mean baseline CES-D score was just below clinical relevance for the usual care group (m = 9.9), with minimal change at three-months (m = 8.9) and six-months (m = 9.5). There were no significant between-group differences in either of the primary outcomes at three-months and six-months (Table 2).

Neither the intervention or usual care group indicated severe anxiety at baseline and there were no significant between-group differences in anxiety at three-months and six-months. The intervention group indicated moderate levels of resilience at baseline (m = 79.8), and the usual care group moderately high resilience (m = 81.4). There were no significant between-group differences in resilience at three-months and six-months. The QCPR data were skewed a multilevel mixed effects generalised linear model with gamma distribution and log link function was applied. The QCPR score was 'good' at baseline for the intervention group (m = 53.0) and the usual care group (m = 54.0). There were no significant between-group differences in the quality of the carer-patient relationship at three-months and six-months. There were no significant between-group differences in the DKAS and the DEMQOL-Proxy at three-months and six-months (Table 2).

Additional unblinded analysis including data on iSupport use found that the number of times logged into iSupport and length of time spent using iSupport did not influence the outcome measures except for the GAD-7 and DEMQOL-Proxy, where using iSupport longer led to a small change in DEMQOL-Proxy scores (coefficient –0.019, p = –0.026; and minimal change in GAD-7 scores (coefficient 0.006, p = 0.023; Appendix p.21). These both demonstrate significant covariate effects in the models but do not alter the significance of the group variables, which remain non-significant treatment effects. Both indicate a negligible change in the covariates and are likely influenced by the low level of usage recorded and therefore should be interpreted with caution.

	Baseline mean (SD)/median [IQR]	T1 mean (SD)/median [IQR]	T2 mean (SD)/median [IQR]	Diff T1 iSupport—Usual Care (mean [95% CI])	Diff T2 iSupport—Usual Care (mean [95% CI])	p-value group
Primary outcomes						
ZBI-12	**Raw data**			**Multi-level mixed effects linear model**		
Usual care	21.7 (7.9)/22 [15, 28]	20.0 (8.0)/20 [14, 26]	20.0 (8.3)/19 [14, 26]	0.67 [−0.57, 1.91]	0.16 [−1.17, 1.49]	0.290
iSupport	21.4 (8.4)/22 [16, 26]	21.1 (8.9)/22 [14.5, 27]	20.6 (8.6)/21 [13, 27]			
CESD-10	**Raw data**			**Multi-level mixed effects linear model**		
Usual care	9.9 (6.3)/8.5 [5,14]	8.9 (6.1)/8 [4, 13]	9.5 (7.0)/8 [5, 13]	0.24 [−0.95, 1.43]	−0.54 [−1.70, 0.62]	0.697
iSupport	10.9 (6.5)/10 [6, 16]	10.2 (6.4)/9 [5, 15]	9.8 (6.5)/10 [4, 14]			
Secondary outcomes						
GAD-7	**Raw data**			**Multi-level mixed effects linear model**		
Usual care	6.3 (4.6)/6 [3, 9]	5.9 (4.7)/5 [2, 8]	5.8 (5.1)/5 [2, 8]	−0.12 [−0.99, 0.76]	0.04 [−0.80, 0.87]	0.791
iSupport	6.4 (4.9)/5 [2, 9]	5.9 (4.5)/5 [3, 8.5]	5.7 (4.9)/5 [2, 8]			
QCPR	**Raw data**			**Multi-level mixed effects generalised linear model with gamma distribution and log link function**		
Usual care	54.0 (9.5)/54 [48,61]	54.3 (9.7)/55 [49, 62]	55.6 (8.9)/58 [51, 62]	−0.01 [−0.03, 0.02]	−0.005 [−0.03, 0.03]	0.683
iSupport	53.0 (10.0)/54 [47, 61]	53.7 (9.4)/55 [48, 60]	54.6 (8.8)/55 [50, 61]			
DKAS	**Raw data**			**Multi-level mixed effects linear model**		
Usual care	32.2 (7.5)/33 [27, 37]	35.0 (7.6)/36 [31, 41]	35.9 (8.0)/36 [32, 42]	−0.07 [−1.25, 1.12]	−0.53 [−1.68, 0.62]	0.912
iSupport	32.2 (7.3)/33 [28, 37]	34.6 (7.3)/35 [30, 39]	35.1 (7.2)/35.5 [30, 40]			
DEMQOL-Proxy	**Raw data**			**Multi-level mixed effects linear model**		
Usual care	87.6 (15.0)/89 [77, 99]	86.7 (17.0)/89 [75, 100]	87.2 (16.5)/89 [74, 100]	1.32 [−1.50, 4.15]	2.04 [−0.67, 4.76]	0.358
iSupport	84.2 (15.6)/86 [73, 95.5]	84.8 (15.4)/85.5 [74.8, 97]	86.7 (16.3)/88 [78, 98]			
RS-14	**Raw data**			**Multi-level mixed effects linear model**		
Usual care	81.4 (11.1)/83.5 [76, 89]	82.2 (10.0)/83 [76.5, 89.5]	81.0 (10.6)/82.5 [74, 89]	−0.65 [−2.40, 1.09]	0.04 [−1.62, 1.69]	0.463
iSupport	79.8 (12.1)/82 [72, 90]	79.9 (11.9)/81 [74, 88]	79.6 (12.8)/81 [71, 90]			

Table 2: **Primary and secondary outcomes.**

The intention was to use quality-adjusted life years (QALYs) as the primary outcome as part of an economic evaluation. However, QALYs were not reported in the economic analysis as the trial did not demonstrate any meaningful QALY gains or losses over time for the intervention group relative to the usual care group. Instead, a complete case analysis of EQ-5D-5L data at baseline and six-months was undertaken as post-hoc analysis (Appendix p.22). There were no significant between-group differences in EQ-5D-5L at six-months ($p = 0.668$).

Further post-hoc analysis included carer relationship (same generation spousal vs. different generation child) and length of time caring (years) as covariates in the models. There was a significant covariate effect for carer relationship; CES-D10 scores were lower in carers who are a different generation (child) to the person with dementia compared to those who are the same generation (coefficient −1.71, $p = 0.003$). There was a significant covariate effect for length of time caring and DKAS scores were lower for those who had been caring for a longer time (coefficient = −0.18, $p = 0.003$). Addition of these covariates did not change the conclusion of treatment effect for the models.

Discussion

Supporting the carers of people living with dementia is an international priority. This is the first large-scale RCT of the WHO's 'iSupport for dementia carers'. Our findings suggest that for informal carers living in the community in England, Wales and Scotland, there was no evidence that the iSupport psychoeducation, skills and self-care programme led to a reduction in distress or depression, and it is unlikely to be cost-effective. There was no evidence for changes in the secondary outcomes of anxiety, resilience, dementia knowledge, the quality of the care relationship. Sensitivity analysis found more time spent using iSupport was negatively related to the quality of life of the person being cared for and anxiety, however the negligible change in the covariates are likely influenced by the low level of usage recorded and therefore should be interpreted with caution.

Given the digital methodology applied in our study recruitment and data collection, we anticipated potential participants would be relatively digitally literate and willing to engage with iSupport. During the development of the funding application we discussed iSupport with a group of people living with dementia and their carers (The Caban Group), who contribute to research and teaching at Bangor university. They commented that 'fear of the internet' was something they were very much aware of amongst their peers, and the online format may discourage people from engaging despite possessing basic IT skills. The group suggested a dedicated person to help participants with iSupport. In response, we built in provision for an 'e-coach' to provide technical support to those randomised to receive iSupport and mitigate against any digital exclusion, albeit restricted to three points of contact. Even with good retention rates and the study offering technical support, we found the engagement with iSupport was low; participants logged in an average of 4 times, although we encouraged participants used it as much as possible in order to gain the most benefits. This is similar to the findings for low engagement in the Portuguese pilot RCT[15] and the Indian RCT,[13] which suggests there are other barriers to iSupport use.

The findings of our trial do not concur with other research, where internet-delivered interventions that combined a personal element showed greater improvements than single mode interventions,[9] or where including minimal human contact in online self-help interventions enhances intervention adherence among carers of people with dementia.[30] Due to the low adherence with iSupport, we suggest the utility of the intervention content may not have been sufficiently tested in this trial.

It may be the personal contact provided in our study should have also included a care professional, peer support or another member of the research team for tailored, therapeutic support and communication rather than practical support with technology alone. Online contact with a professional can provide personalised practical advice and emotional support, leading to a reduction in burden and strain.[31] It is suggested that supportive listening, providing guidance, and motivational or social support may influence online intervention adherence and improve outcomes.[30] For example in other populations, a cardiovascular risk management online intervention with remote support from a coach trained in motivational interviewing and lifestyle behaviour advice led to modest improvements in cardiovascular risk profiles in people aged 65 and over compared to controls.[32] Personal contact could also consider facilitating the identification of baseline goals and subsequent matching to relevant iSupport modules, an approach found to be effective in achieving goal attainment in an intervention for people with dementia and carer dyads.[33]

We chose the self-guided option for the following reasons: First, this is a most likely reflection of how iSupport would be delivered in a national roll-out, given the current challenges in the UK health and social care service provision; Second, following the COVID-19 pandemic, many health and care services have retained online service delivery as part of mainstream care; Third, the lack of care professionals and services in many low and middle-income countries means iSupport as a self-guided intervention may be one of the very few resources available to carers. Finally, the version of iSupport tested in this trial is the same as the version provided to the public by the WHO. On that basis, we

felt a 'real world' evaluation of iSupport as a self-guided intervention was necessary and would potentially lead to more generalisable results. It was possible to access the WHO generic version of iSupport, although this is not widely promoted in the UK and a wider implementation drive was planned to follow on from this study. In order for the control participants to access the WHO generic version, they would have needed to create their own online account first, which asks for a considerable amount of personal detail and is a fairly convoluted process. Nevertheless, to try and mitigate against this we included a note in the randomisation email sent to all control participants informing them we would provide access to iSupport UK (our study version) at the end of their involvement. We also aimed to avoid recruiting people who had already engaged with iSupport, and one of the eligibility criteria was that participants had not previously used iSupport materials in the last 12 months. This was checked in the participant screening ahead of enrolment into the study.

Given the digital literacy of the participants, the null findings were not anticipated. As translations and cultural adaptations, early-stage feasibility studies, and plans for evaluations of iSupport are underway around the world (Appendix pp 23–25), we recommend exploring the feasibility of combined modes of delivery that include an element of human contact beyond technical support, especially the extent to which these combined modes of delivery could be implemented if successful. A recent online multicomponent RCT conducted with Chinese carers in Australia and China combined the iSupport programme with monthly facilitator led meetings and peer support and found the intervention group had significantly higher scores than the usual group for mental-health-related quality of life, self-efficacy in controlling upsetting thoughts, and lower score of distress reactions to changed behaviours.[34]

Further Adaptations of iSupport for different cultural settings and populations that include amending the original content, language and presentation may lead to a better, more refined and effective product for implementation. Further research of self-guided online interventions should also consider more frequent contact with participants than applied in this trial to encourage engagement with the content.

Our study has significant strengths. iSupport is safe to deliver, evidenced by no adverse events linked to study participation. Given the complexity of informal care roles, carers are often difficult to recruit into research despite their importance to advancing knowledge, and sample sizes are often smaller than required for statistical power, leading to inconclusive results.[35,36] Our methods are transparent and reproduceable, and we successfully recruited a large sample of dementia carers (352) across geographically diverse areas in England, Wales and Scotland in accordance with our sample size calculation. Our study had good retention rates by the final follow up at six-months (74.7%) as per our planned protocol. This contrasts with the feasibility RCT in India where attrition was high and the study retention rate was only 36.42%.[13] The timelines for a trial of this nature requires a rapid phase of recruitment, and while we successfully recruited to target, a limitation is the sample lacks diversity; participants were predominantly white, well-educated and English speaking, with only five participants noting another main language. Notably, our recruitment efforts in Wales led to only two participants stating Welsh as their main language. Research funders may need to consider the additional activities and subsequent impact on timelines (and resources) for future funding in order to enable the successful recruitment of underserved, diverse populations of carers into studies.

The carer characteristics are also an important consideration in terms of low engagement in the intervention arm of the trial. The participants had already spent an average of three years in their caring role. They may have adapted to their circumstances and already sought out or have been provided with information and support. In this respect, iSupport may have been useful but re-stated much of what they already knew. The baseline levels of resilience were categorised as moderate for the intervention group and moderately high for the usual care group, which indicate that despite also reporting high levels of distress and clinically relevant symptoms of depression at baseline, the participants were being supported to enable a resilience response to their role. This is further reflected in the 'good' baseline score for the quality of the relationship with the person they care for. iSupport may then be more relevant when provided early at the point of diagnosis. However we found that more time spent using iSupport was negatively related to the quality of life of the person being cared for, which suggests the content may have increased carers awareness and impacted on their perceptions. This further reinforces the suggestion for professional guidance alongside self-guided delivery to enable carers to discuss their experiences. We would also suggest that goal-focussed outcomes that are more personalised to carers may be useful outcomes when assessing self-guided interventions such as iSupport alongside some professional support.

The null findings from this robust trial address a major limitation of self-guided digital intervention research for dementia carers, where evidence of effectiveness to date have mainly been reported from low quality research,[9,37] possibly influenced by bias towards publishing positive results. The low use of iSupport in this study points to wider limitations in self-guided online interventions, which are increasingly becoming part of mainstream care delivery as part of the digital transformations in health and social care.[38] These may be especially limiting in countries where carers can

access a range of services. However, in low and middle-income countries where resources for carers are limited and professional support is minimal or not available, cultural and linguistic adaptations of iSupport, perhaps including low intensity human support, will be an important resource in dementia care. The results from this trial will inform the direction of the global implementation of iSupport by the WHO and assist the decision making of national health and care providers in prioritising resources towards effective interventions and their effective implementation.

Contributors

GW responsible for conceptualization of the study, led the funding acquisition, contributed to methodology, project administration, resources, supervision, led the writing of the manuscript; GF managed the trial, contributed to data curation, methodology, project administration, software, reviewing and editing the manuscript, accessed and verified the data. JS contributed to funding acquisition, methodology, resources, supervision, reviewing and editing the manuscript, led administration for the England site; KE contributed to funding acquisition, methodology, resources, supervision, reviewing the manuscript, led administration for the Scotland site; ZH contributed to funding acquisition, methodology, resources, project administration, supervision, reviewing and editing the manuscript, led formal analysis; software and data curation; NG contributed to data curation, formal analysis, methodology, project administration, software, reviewing and editing the manuscript, data curation, prepared Tables 1 and 2, has accessed and verified the data; RTE contributed to funding acquisition, methodology, resources, supervision, formal analysis, reviewing and editing the manuscript; BA contributed to formal analysis, reviewing and editing the manuscript, has directly accessed and verified the data; PMA contributed to funding acquisition, methodology, resources, supervision, reviewing and editing the manuscript; SK contributed to investigation, project administration, reviewing manuscript; AS contributed to methodology, resources, supervision, reviewing and editing the manuscript; GH contributed to funding acquisition, investigation, project administration, reviewing manuscript; RI contributed to funding acquisition, investigation, project administration, reviewing manuscript; JC contributed to funding acquisition, investigation, project administration, reviewing manuscript; DP contributed to funding acquisition, investigation, project administration, reviewing manuscript; FAI contributed to funding acquisition, investigation, project administration, reviewing manuscript; KJ contributed to funding acquisition, investigation, project administration, reviewing manuscript. All authors reviewed the manuscript and had final responsibility for the decision to submit for publication.

Data sharing statement

The datasets generated and analysed during the study are available upon request. Access to deidentified data may be granted following review and approval. All data requests should be submitted to the corresponding author for consideration.

Declaration of interests

All authors were either applicants or staff on the research programme that funded this trial. GH was a non-voting steering committee member due to being an expert by experience. PMA and GW are members of the WHO iSupport international network and received funding from a Bangor University Innovation and Impact Award to further develop 'iSupport for Young People' in Brazil and Spain. JS is the primary investigator on three funded projects unrelated to this work. KE is a primary investigator on two informal carer projects (including innovations for physical activity and employment) which are unrelated to iSupport.

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National collaborating partners in iSupport: Carers Trust Wales; Alzheimer Scotland.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.lanepe.2024.101125.

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