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Effects of an e-health intervention 'iSupport' for reducing distress of dementia carers

Submission date
27/11/2020

Recruitment status
No longer recruiting

Registration date
09/03/2021

Overall study status
Completed

Last Edited
19/05/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
NHS guidelines recommend informal carers of people living with dementia such as family and friends should be offered training to help them develop care skills and manage their own physical and mental health. The World Health Organisation recommend access to affordable, proven, well-designed, online technologies for education, skills training and support for dementia carers. In response to these recommendations, this is the first study in the UK of the benefits of an online training and support programme. This was developed by the World Health Organisation and is called 'iSupport'. It is designed for dementia carers to help them provide good care and take care of themselves. Carers can use iSupport at their own pace. They can access whichever parts of iSupport they feel are most relevant to them from their place of choice using a computer, tablet or smartphone. It is important to do this work because most people living with dementia are cared for at home, supported by a family member or friend who has limited knowledge of the condition. The role is very stressful, and many carers experience more mental and physical illness compared to people who are not dementia carers. COVID-19 has meant that many older people have to self-isolate, placing increasing pressures on carers. The aim of this study is to examine the effectiveness of iSupport in reducing distress.

Who can participate?
Dementia carers aged 18+ years in England, Wales and Scotland, and 30 young carers

What does the study involve?
Half of the carers will complete iSupport and half will receive information leaflets. All the carers will answer questionnaires about stress and strain, mental health, resilience and knowledge of dementia. They will do this three times over a 6-month period. By comparing the two groups, the researchers will be able to show whether iSupport is better than simply giving information. To understand what aspects of iSupport carers like the most, and what might put them off using it, the researchers will undertake interviews with a smaller group (50) of the carers and have a longer discussion about their thoughts, feelings and the impact of iSupport on themselves. They will do this three times over a 6-month period. To examine the potential costs and benefits of iSupport carers will answer questions about health and social care service use and their quality of life. They will do this three times over a 6-month period. There are currently no evidence-based support interventions for young carers of people with dementia. The researchers will

work with a group of young carers and adapt iSupport for their use, identify what outcomes are most important to them, and assess this new version of iSupport with 30 young carers.

Where is the study run from?
The study is run from Bangor University in Wales, with partners in the University of Strathclyde, Scotland and UCL in England

When is it starting and how long will it run for?
October 2020 to June 2024

Who is funding the study?
National Institute for Health Research - Public Health Research Programme (UK)

Who is the main contact?
Prof. Gill Windle
g.windle@bangor.ac.uk

Study website
https://dsdc.bangor.ac.uk/isupport-for-dementia-carers.php.en

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
311565

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PHR - NIHR130914, IRAS 311565

Study information

Scientific Title
A randomized controlled trial and feasibility study of the effects of an e-health intervention ‘iSupport’ for reducing distress of dementia carers

Acronym
iSupport

Study objectives
1. Is carer distress and/or symptoms of depression (primary outcomes) significantly reduced in participants allocated to receive iSupport compared to participants allocated to a comparison group?
2. Are symptoms of anxiety (secondary outcome) significantly reduced, and resilience, relationship quality and dementia knowledge (secondary outcomes) significantly increased in participants allocated to receive iSupport compared to participants allocated to a comparison group receiving standardised information about dementia?
3. What are the participant and contextual barriers and facilitators to the implementation of iSupport?
4. What potential mechanisms might underpin changes in outcomes from using iSupport?
5. What is the cost-effectiveness of iSupport compared to standardised information about dementia?
6. What are the carers’ perspectives of iSupport in relation to supporting them in an ongoing or future repeated pandemic such as COVID-19?

The feasibility study will assess if it is feasible, useful and acceptable to refine and digitally deliver a refined iSupport to young carers.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 12/04/2021, Bangor University School of Medical and Health Sciences Academic Ethics Committee (AEC) (Bangor University, College Road, Bangor, LL57 2DG, United Kingdom; +44 1248 351 151; hcmsethics@bangor.ac.uk), ref: 2021-16915

2. Approved 02/11/2022, London - City & East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048171; cityandeast.rec@hra.nhs.uk), ref: 22/LO/0688

Study design
Trial: multi-centre pragmatic single-blinded two-arm randomized controlled trial with an internal pilot
Feasibility study: non-randomized feasibility study of intervention refinement for younger dementia carers

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Reductions in psychological distress and improvements in skills and resilience in dementia carers

Interventions
WS1 is a multi-centre, pragmatic, single-blinded, two-arm randomized controlled trial (RCT) with an internal pilot. Randomization through a secure online system employing a dynamic randomisation algorithm will allocate patients to the intervention or control-comparison group. Participants assigned to the control-comparison group will receive information about dementia developed by the Alzheimer's Society. A 6-month internal pilot will be nested in this WS at each site. Stop/Review/Go criteria will indicate the success of the participant recruitment targets (e.g. 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: 56-93 (50 - 84%), Stop: <=55 (<50%)). The study is guided by the 'Context and Implementation of Complex Interventions' checklist.

WS2 PROCESS EVALUATION will run alongside WS1 and apply mixed-methods (semi-structured interviews, quantitative questionnaires and analysis of data from the online platform). It will be conducted in line with established guidance frameworks. It will examine throughout the intervention period how participants engage with and adhere to particular aspects of iSupport (e.g. most/least frequently visited pages, the most 'popular' modules/sessions, sessions with quizzes with the highest rates of wrong responses). A System Usability Scale will be administered at 6-month follow up. This 10-item scale will quantitatively evaluate the overall usability of the iSupport platform. Semi-structured interviews will be undertaken using an internet-based service (e.g. Zoom, Teams, Skype, or GoToMeeting) or telephone, with a sub-sample of the intervention participants. These will be recorded and professionally transcribed. The topic guides will be guided by the process evaluation parameters described in recognised frameworks.

WS3 HEALTH ECONOMICS will evaluate the cost-effectiveness of iSupport from a public sector perspective. The cost of implementing iSupport (e.g., time spent supporting carers to use the tool, and the cost of maintaining technical support for the tool) will be calculated.

WS4 A NON-RANDOMIZED FEASIBILITY STUDY will refine iSupport through co-design workshops with young carers. It will identify what outcomes are most important to young carers in relation to iSupport, and then explore the refined programme. Success will be defined as acceptability of the: a) recruitment process, b) assessments, c) data collection tools, d) intervention content & delivery to participants, as well as compliance. This work will be undertaken in line with WHO's iSupport version 1.0. Adaptation and implementation guide for international uptake.

Intervention Type
Behavioural

Primary outcome measure
There will be two primary outcome measures for WS1. Sample size has been based on considering both outcomes as primary outcomes where a successful trial would be noted if at least one of the outcomes indicated a statistically significant effect. Both primary outcome measures will be administered at baseline (T0), 3 months after baseline (T1) and 6 months after baseline (T2):
1. Carers' distress measured by the 12-item Zarit Burden Interview (ZBI-12)
2. Caregiver depression measured by the 10-item Centre for Epidemiological Studies of Depression Scale (CES-D 10)

Secondary outcome measures
Current secondary outcome measures as of 04/03/2024:

1. The frequency of common symptoms of anxiety assessed through the Generalised Anxiety Disorder Questionnaire (GAD-7)
2. Improvements in the way carers perceive they can manage the situation assessed through the Resilience Scale-14 (RS-14)
3. The influence of iSupport on the quality of the caregiving relationship assessed through the 14-item Quality of the Carer-Patient Relationship (QCPR)
4. Improvements in how the carer understands their relative assessed through the 25-item Dementia Knowledge Assessment Scale (DKAS)
5. Utility values for Quality-Adjusted Life Years obtained from responses to the EQ-5D-5L
6. Impact on the health-related quality of life of the person being cared for assessed through the DEMQOL-Proxy
7. Out of pocket expenses obtained through a Service Use Questionnaire developed for iSupport
8. Opportunity costs assessed through the iMTA Valuation of Informal Care Questionnaire

The feasibility study (WS4) will adapt the standardised measures above based on focus group responses, and conduct the assessments with younger dementia carers at baseline (T0), 3 months after baseline (T1) and 6 months after baseline (T2).

One measure, the Short Sense of Competence Questionnaire (SSCQ), was agreed with NIHR to remove from the case report form (CRF) due to overlap with other measures..

Measured at baseline (T0), 3 months after baseline (T1) and 6 months after baseline (T2):
1. The frequency of common symptoms of anxiety assessed through the Generalised Anxiety Disorder Questionnaire (GAD-7)

2. Improvements in the way carers perceive they can manage the situation assessed through the Resilience Scale-14 (RS-14)
3. The influence of iSupport on the quality of the caregiving relationship assessed through the 14-item Quality of the Carer-Patient Relationship (QCPR)
4. Improvements in how the carer understands their relative assessed through the 25-item Dementia Knowledge Assessment Scale (DKAS)
5. Utility values for Quality-Adjusted Life Years obtained from responses to the EQ-5D-5L
6. Impact on the health-related quality of life of the person being cared for assessed through the DEMQOL-Proxy
7. Out of pocket expenses obtained through a Service Use Questionnaire developed for iSupport
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The feasibility study (WS4) will adapt the standardised measures above based on focus group responses, and conduct the assessments with younger dementia carers at baseline (T0), 3 months after baseline (T1) and 6 months after baseline (T2).

One measure, the Short Sense of Competence Questionnaire (SSCQ), was agreed with NIHR to remove from the case report form (CRF) due to overlap with other measures.

Previous secondary outcome measures:

Measured at baseline (T0), 3 months after baseline (T1) and 6 months after baseline (T2):
1. The frequency of common symptoms of anxiety assessed through the Generalised Anxiety Disorder Questionnaire (GAD-7)
2. Improvements in the way carers perceive they can manage the situation assessed through the Resilience Scale-14 (RS-14)
3. Sense of competence developed for dementia caregivers assessed through the 7-item Short Sense of Competence Questionnaire (SSCQ)
4. The influence of iSupport on the quality of the caregiving relationship assessed through the 14-item Quality of the Carer-Patient Relationship (QCPR)
5. Improvements in how the carer understands their relative assessed through the 25-item Dementia Knowledge Assessment Scale (DKAS)
6. Utility values for Quality-Adjusted Life Years obtained from responses to the EQ-5D-5L
7. Impact on the health-related quality of life of the person being cared for assessed through the DEMQOL-Proxy
8. Out of pocket expenses obtained through a Service Use Questionnaire developed for iSupport
9. Opportunity costs assessed through the iMTA Valuation of Informal Care Questionnaire

The feasibility study (WS4) will adapt the standardised measures above based on focus group responses, and conduct the assessments with younger dementia carers at baseline (T0), 3 months after baseline (T1) and 6 months after baseline (T2).

Overall study start date
01/10/2020

Completion date
30/06/2024

Eligibility

Key inclusion criteria
WS1 & WS3
Dementia carers (age 18+ years):
1. Self-identify as an unpaid carer (partners, children, friends, etc.) of a person with dementia who is not living in a full-time care facility, caring at least weekly for at least 6 months
2. Self-identify as experiencing at least some stress, depression or anxiety
3. The care recipient has to have a confirmed diagnosis of dementia (through self-report by the carer, to reflect the 'real world' application of iSupport)

WS2 PROCESS EVALUATION will run alongside WS1 to undertake a mixed-methods exploration in line with Medical Research Council guidance. It will assess the implementation of iSupport, the participant's perspectives of the intervention, including the barriers, facilitators and perceived benefits, and theorize mechanisms of change

WS4
Young dementia carers (age 11-17 years):
1. Young people between the age of 11-17 years (secondary school age) who self-identify as a carer of a person with dementia who is not living in a full-time care facility, caring at least weekly for at least 6 months
2. The care recipient has to have a confirmed diagnosis of dementia (through self-report by the carer, to reflect the 'real world' application of iSupport)

Participant type(s)
Carer

Age group
Mixed

Lower age limit
11 Years

Sex
Both

Target number of participants
350

Total final enrolment
352

Key exclusion criteria
Trial exclusion criteria:
1. Receiving psychological treatment from a mental health specialist at the time of recruitment
2. Unable to comprehend written English
3. No access to the internet
4. Unable to give informed consent to the trial
5. Have previously used iSupport materials (in the last 12 months)

Feasibility study (WS4) exclusion criteria:
1. Receiving treatment from Child and Adolescent Mental Health Services (CAMHS) at the time of recruitment

2. Unable to comprehend written English
3. No access to the internet
4. Have previously used iSupport materials (in the last 12 months)

Date of first enrolment
01/12/2021

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
North Wales Organisation for Randomised Trials in Health (NWORTH)
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Sponsor type

University/education

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ROR
https://ror.org/006jb1a24

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Additional documents will be available at a later stage. A comprehensive pathway to impact plan and communication strategy will be developed at the outset. In addition to stakeholder events, conferences and publications, the implementation hub draws together key stakeholders at the forefront of public health policy and practice to facilitate the reach and impact of the findings.

Intention to publish date
30/09/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Gill Windle (g.windle@bangor.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		21/09/2022	22/09/2022	Yes	No
Statistical Analysis Plan	version 1	29/09/2023	04/03/2024	No	No
Basic results	version 1	27/09/2024	27/09/2024	No	No
Results article		20/11/2024	28/11/2024	Yes	No
Other publications	Cost-consequence analysis	16/05/2025	19/05/2025	Yes	No