CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form

The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating web-based and Internet-based applications/interventions, including mobile interventions, electronic games (incl multiplayer games), social media, certain telehealth applications, and other interactive and/or networked electronic applications. Some of the items (e.g. all subitems under item 5 - description of the intervention) may also be applicable for other study designs.

The goal of the CONSORT EHEALTH checklist and guideline is to be
a) a guide for reporting for authors of RCTs,
b) to form a basis for appraisal of an ehealth trial (in terms of validity)

CONSORT-EHEALTH items/subitems are MANDATORY reporting items for studies published in the Journal of Medical Internet Research and other journals / scientific societies endorsing the checklist.

Items numbered 1., 2., 3., 4a., 4b etc are original CONSORT or CONSORT-NPT (non-pharmacologic treatment) items.
Items with Roman numerals (i., ii, iii, iv etc.) are CONSORT-EHEALTH extensions/clarifications.

As the CONSORT-EHEALTH checklist is still considered in a formative stage, we would ask that you also RATE ON A SCALE OF 1-5 how important/useful you feel each item is FOR THE PURPOSE OF THE CHECKLIST and reporting guideline (optional).

Mandatory reporting items are marked with a red *.
In the textboxes, either copy & paste the relevant sections from your manuscript into this form - please include any quotes from your manuscript in QUOTATION MARKS,
or answer directly by providing additional information not in the manuscript, or elaborating on why the item was not relevant for this study.

YOUR ANSWERS WILL BE PUBLISHED AS A SUPPLEMENTARY FILE TO YOUR PUBLICATION IN JMIR AND ARE CONSIDERED PART OF YOUR PUBLICATION (IF ACCEPTED).
Please fill in these questions diligently. Information will not be copyedited, so please use proper spelling and grammar, use correct capitalization, and avoid abbreviations.

DO NOT FORGET TO SAVE AS PDF _AND_ CLICK THE SUBMIT BUTTON SO YOUR ANSWERS ARE IN OUR DATABASE !!!

Citation Suggestion (if you append the pdf as Appendix we suggest to cite this paper in the caption):
Eysenbach G, CONSORT-EHEALTH Group
CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions
J Med Internet Res 2011;13(4):e126

URL: http://www.jmir.org/2011/4/e126/
doi: 10.2196/jmir.1923
PMID: 22209829

登录 Google 即可保存进度。了解详情

* 表示必填

Your name *

First Last

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University of Toronto, Toronto, Canada

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Your e-mail address *

abc@gmail.com

hsyhly2012@qq.com

Title of your manuscript *

Provide the (draft) title of your manuscript.

Internet-Based Supportive Interventions for Family Caregivers of People With Dementia: A Randomized Controlled Trial

Name of your App/Software/Intervention *

If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

Internet-Based Supportive Interventions

Evaluated Version (if any)

e.g. "V1", "Release 2017-03-01", "Version 2.0.27913"

Version 1.0

Language(s) *

What language is the intervention/app in? If multiple languages are available, separate by comma (e.g. "English, French")

Chinese

URL of your Intervention Website or App

e.g. a direct link to the mobile app on app in appstore (itunes, Google Play), or URL of the website. If the intervention is a DVD or hardware, you can also link to an Amazon page.

61.175.192.169:9234/login.aspx

URL of an image/screenshot (optional)

您的回答

Accessibility *

Can an enduser access the intervention presently?

- ○ access is free and open
- ○ access only for special usergroups, not open
- ○ access is open to everyone, but requires payment/subscription/in-app purchases
- ◉ app/intervention no longer accessible
- ○ 其他:

Primary Medical Indication/Disease/Condition *

e.g. "Stress", "Diabetes", or define the target group in brackets after the condition, e.g. "Autism (Parents of children with)", "Alzheimers (Informal Caregivers of)"

Informal Caregivers of Dementia

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

NPI-Q, CZBI, SCIDS

Secondary/other outcomes

Are there any other outcomes the intervention is expected to affect?

There are no other outcomes.

Recommended "Dose" *

What do the instructions for users say on how often the app should be used?

- ○ Approximately Daily
- ◉ Approximately Weekly
- ○ Approximately Monthly
- ○ Approximately Yearly
- ○ "as needed"
- ○ 其他:

Approx. Percentage of Users (starters) still using the app as recommended after 3 months *

- ○ unknown / not evaluated
- ○ 0-10%
- ○ 11-20%
- ○ 21-30%
- ◉ 31-40%
- ○ 41-50%
- ○ 51-60%
- ○ 61-70%
- ○ 71%-80%
- ○ 81-90%
- ○ 91-100%
- ○ 其他:

Overall, was the app/intervention effective? *

- (●) yes: all primary outcomes were significantly better in intervention group vs control
- ( ) partly: SOME primary outcomes were significantly better in intervention group vs control
- ( ) no statistically significant difference between control and intervention
- ( ) potentially harmful: control was significantly better than intervention in one or more outcomes
- ( ) inconclusive: more research is needed
- ( ) 其他:

Article Preparation Status/Stage *

At which stage in your article preparation are you currently (at the time you fill in this form)

- ( ) not submitted yet - in early draft status
- ( ) not submitted yet - in late draft status, just before submission
- ( ) submitted to a journal but not reviewed yet
- (●) submitted to a journal and after receiving initial reviewer comments
- ( ) submitted to a journal and accepted, but not published yet
- ( ) published
- ( ) 其他:

Journal *

If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other")

- ○ not submitted yet / unclear where I will submit this
- ○ Journal of Medical Internet Research (JMIR)
- ○ JMIR mHealth and UHealth
- ○ JMIR Serious Games
- ○ JMIR Mental Health
- ○ JMIR Public Health
- ○ JMIR Formative Research
- ◉ Other JMIR sister journal
- ○ 其他:

Is this a full powered effectiveness trial or a pilot/feasibility trial? *

- ◉ Pilot/feasibility
- ○ Fully powered

Manuscript tracking number *

If this is a JMIR submission, please provide the manuscript tracking number under "other" (The ms tracking number can be found in the submission acknowledgement email, or when you login as author in JMIR. If the paper is already published in JMIR, then the ms tracking number is the four-digit number at the end of the DOI, to be found at the bottom of each published article in JMIR)

- ○ no ms number (yet) / not (yet) submitted to / published in JMIR
- ◉ 其他: JMIR Aging #50847

TITLE AND ABSTRACT

1a) TITLE: Identification as a randomized trial in the title

1a) Does your paper address CONSORT item 1a? *

I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")

- (●) yes
- ( ) 其他:

1a-i) Identify the mode of delivery in the title

Identify the mode of delivery. Preferably use “web-based” and/or “mobile” and/or “electronic game” in the title. Avoid ambiguous terms like “online”, “virtual”, “interactive”. Use “Internet-based” only if Intervention includes non-web-based Internet components (e.g. email), use “computer-based” or “electronic” only if offline products are used. Use “virtual” only in the context of “virtual reality” (3-D worlds). Use “online” only in the context of “online support groups”. Complement or substitute product names with broader terms for the class of products (such as “mobile” or “smart phone” instead of “iphone”), especially if the application runs on different platforms.

subitem not at all important

- 1 ( )
- 2 ( )
- 3 ( )
- 4 ( )
- 5 (●)

essential

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Does your paper address subitem 1a-i? *

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

JA - #50847 Review (jmir.org)

1a-ii) Non-web-based components or important co-interventions in title

Mention non-web-based components or important co-interventions in title, if any (e.g., “with telephone support”).

subitem not at all important

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Does your paper address subitem 1a-ii?

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Internet-Based Supportive Interventions for Family Caregivers of People With Dementia: A Randomized Controlled Trial

1a-iii) Primary condition or target group in the title

Mention primary condition or target group in the title, if any (e.g., “for children with Type I Diabetes”) Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial

subitem not at all important

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Does your paper address subitem 1a-iii? *

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“The intervention group received caregiver skill training based on an online platform, while the control group received face-to-face follow-up guidance and then received online training after 6 months. ”

1b) ABSTRACT: Structured summary of trial design, methods, results, and conclusions

NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status.

1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT

Mention key features/functionalities/components of the intervention and comparator in the abstract. If possible, also mention theories and principles used for designing the site. Keep in mind the needs of systematic reviewers and indexers by including important synonyms. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

subitem not at all important

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Does your paper address subitem 1b-i? *

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Background: As dementia progresses, patients exhibit various psychological and behavioral symptoms, placing a heavy burden on families and society. However, caregivers lack professional care knowledge and skills, making it difficult for them to effectively cope with the diverse challenges of caregiving. Therefore, it is urgent to provide caregivers with professional knowledge and skills guidance.
Objective:This study aimed to analyze the impact of Internet-based Online Training on the care burden and caregiving abilities of dementia caregivers.
Design:According to a consecutive enrollment method, the Department of Geriatrics of Zhejiang Hospital (Zhejiang China) recruited 72 informal caregivers for dementia patients, divided into an intervention group and a control group, with 36 cases in each group. The intervention group received caregiver skill training based on an online platform, while the control group received face-to-face follow-up guidance and then received online training after 6 months. To evaluate the effectiveness of the intervention program, researchers used the Neuropsychiatric Inventory-Questionnaire (NPI-Q), the Chinese version of Zarit Caregiver Burden Interview (CZBI), and the Severe Cognitive Impairment Dementia Scale (SCIDS) for assessment before the intervention, 3 months after the intervention, and 6 months after the intervention.
Results： Between July 2019 and December 2020， a total of 66 patients successfully completed the intervention and follow-up. After 6 months of intervention, the NPI-Q score of the intervention group was 3.18 ± 3.81, the CZBI score was 10.97±5.43, and the SCIDS score was 71.88± 4.78. The NPI-Q score of the control group was 8.09 ± 8.52, the CZBI score was 30.30 ± 13.05, and the SCIDS score was 50.12 ± 9.10. The differences between the groups were statistically significant (P<0.05). Repeated measures analysis of variance showed significant improvements in NPI-Q,CZBI, and SCIDS total scores in the intervention group at 3 and 6 months post-intervention compared to pre-intervention (P<0.05). Furthermore, covariance analysis results demonstrated that the online training intervention program significantly reduced NPI-Q scores in dementia patients and CZBI scores in caregivers while increasing SCIDS scores, after excluding time effects (P<0.05).
Conclusion: Online training based on the internet could significantly reduce the level of behavioral symptoms in elderly patients with dementia and alleviate the burden on caregivers, enhancing their caregiving abilities. The research results fully confirmed the effectiveness and feasibility of online training, which was of great significance in providing caregiving knowledge training for informal caregivers of persons with dementia.”

1b-ii) Level of human involvement in the METHODS section of the ABSTRACT

Clarify the level of human involvement in the abstract, e.g., use phrases like “fully automated” vs. “therapist/nurse/care provider/physician-assisted” (mention number and expertise of providers involved, if any). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

subitem not at all important

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Does your paper address subitem 1b-ii?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“An RCT design was employed to study the feasibility and effectiveness of a nurse-led multidisciplinary team online training and support program.”

1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT

Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic or a closed online user group (closed usergroup trial), and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment). Clearly say if outcomes were self-assessed through questionnaires (as common in web-based trials). Note: In traditional offline trials, an open trial (open-label trial) is a type of clinical trial in which both the researchers and participants know which treatment is being administered. To avoid confusion, use “blinded” or “unblinded” to indicated the level of blinding instead of “open”, as “open” in web-based trials usually refers to “open access” (i.e. participants can self-enrol). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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Does your paper address subitem 1b-iii?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“In the intervention group, we instructed the informal caregivers of persons with dementia to log in to the platform web page and taught them about the knowledge and skills relevant to home care through the internet.”

1b-iv) RESULTS section in abstract must contain use data

Report number of participants enrolled/assessed in each group, the use/uptake of the intervention (e.g., attrition/adherence metrics, use over time, number of logins etc.), in addition to primary/secondary outcomes. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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Does your paper address subitem 1b-iv?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

In the follow-up period, 3 patients in the intervention group and the control group were lost to follow-up, respectively. In the intervention group, two caregivers accompanied the dementia patients as they relocated to a different city, and another caregiver returned to her hometown after the dementia patient was admitted to a nursing home. In the control group, one caregiver accompanied the dementia people emergency admission who suffered a fracture, another caregiver failed to continue to contact after repeated appointments, and one caregiver accompanied patient to a nursing home ”

1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials

Conclusions/Discussions in abstract for negative trials: Discuss the primary outcome - if the trial is negative (primary outcome not changed), and the intervention was not used, discuss whether negative results are attributable to lack of uptake and discuss reasons. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

subitem not at all important

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Does your paper address subitem 1b-v?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The results of this study are all positive, so there is no relevant discussion on negative results.

INTRODUCTION

2a) In INTRODUCTION: Scientific background and explanation of rationale

2a-i) Problem and the type of system/solution

Describe the problem and the type of system/solution that is object of the study: intended as stand-alone intervention vs. incorporated in broader health care program? Intended for a particular patient population? Goals of the intervention, e.g., being more cost-effective to other interventions, replace or complement other solutions? (Note: Details about the intervention are provided in “Methods” under 5)

subitem not at all important

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Does your paper address subitem 2a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“The platform aims to provide opportunities for support, education, and sharing experiences between users across the Zhejiang province. ”“The content on the platform was divided into five different themes, which were: computer cognitive training, language training, reality-oriented therapy, daily life rehabilitation, and care skills training. Computer cognitive training includes concentration (picture-text matching), memory (vocabulary memorization), calculation (simulated shopping), and reaction training (fruit picking). Each training time is 20 minutes, conducted three times a week. Language training aims at improve communication by focusing on vocalization, recognition, and application of words. Reality orientation therapy focuses on presenting patients with facts about the time, date, and current environment. The primary objective for daily life rehabilitation is to increase self-care ability. ”

2a-ii) Scientific background, rationale: What is known about the (type of) system

Scientific background, rationale: What is known about the (type of) system that is the object of the study (be sure to discuss the use of similar systems for other conditions/diagnoses, if appropiate), motivation for the study, i.e. what are the reasons for and what is the context for this specific study, from which stakeholder viewpoint is the study performed, potential impact of findings [2]. Briefly justify the choice of the comparator.

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Does your paper address subitem 2a-ii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“This manuscript presents the findings of a randomized controlled trial (RCT) examining the implementation of an internet-based supportive interventionsfor home care among patients with dementia in China. The trial is an innovative online support program that was developed to advance the skills, knowledge, and practice of caregivers, in order to enhance self-care skills in individuals with dementia and simultaneously provide invaluable assistance for their caregivers.”

2b) In INTRODUCTION: Specific objectives or hypotheses

Does your paper address CONSORT subitem 2b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“It was hypothesized that internet-based supportive interventions would produce greater “improvement in primary outcomes than routine caregiving interventions after discharge. ”

METHODS

3a) Description of trial design (such as parallel, factorial) including allocation ratio

Does your paper address CONSORT subitem 3a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Baseline information was collected by trained interviewers from participants through completing standardized questionnaires. During the interviews, trained interviewers were blinded to the group allocations. Participants were randomly allocated on a 1:1 ratio assigned to either the intervention or a waiting list control group after baseline assessment. Randomization was carried out using a random number generator. ”

3b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons

Does your paper address CONSORT subitem 3b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

There were no important changes to methods after the experiment started.

3b-i) Bug fixes, Downtimes, Content Changes

Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes important changes made on the intervention or comparator during the trial (e.g., major bug fixes or changes in the functionality or content) (5-iii) and other “unexpected events” that may have influenced study design such as staff changes, system failures/downtimes, etc. [2].

subitem not at all important

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Does your paper address subitem 3b-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“In the follow-up period, 3 patients in the intervention group and the control group were lost to follow-up, respectively. In the intervention group, two caregivers accompanied the dementia patients as they relocated to a different city, and another caregiver returned to her hometown after the dementia patient was admitted to a nursing home. In the control group, one caregiver accompanied the dementia people emergency admission who suffered a fracture, another caregiver failed to continue to contact after repeated appointments, and one caregiver accompanied patient to a nursing home (Fig.1).

4a) Eligibility criteria for participants

Does your paper address CONSORT subitem 4a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Selection criteria included:(1) Being a primary, informal caregiver aged at least 18 years; (2)Caring for individuals with dementia while living together at home for a minimum of six months.; (3) having Internet access to computers or iPads; (4) could read, understand Chinese and following instructions. Participants were excluded if they had severe visual or hearing impairment incompatible with participation as assessed by the study staff. ”

4a-i) Computer / Internet literacy

Computer / Internet literacy is often an implicit “de facto” eligibility criterion - this should be explicitly clarified.

subitem not at all important

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Does your paper address subitem 4a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Selection criteria included: (3) having Internet access to computers or iPads; (4) could read, understand Chinese and following instructions.

4a-ii) Open vs. closed, web-based vs. face-to-face assessments:

Open vs. closed, web-based vs. face-to-face assessments: Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic, and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment), i.e., to what degree got the study team to know the participant. In online-only trials, clarify if participants were quasi-anonymous and whether having multiple identities was possible or whether technical or logistical measures (e.g., cookies, email confirmation, phone calls) were used to detect/prevent these.

subitem not at all important

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Does your paper address subitem 4a-ii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“The trial was designed, planned, and executed by the Department of Geriatrics of Zhejiang Hospital (Zhejiang China). An RCT design was employed to study the feasibility and effectiveness of a nurse-led multidisciplinary team online training and support program. From July 2019 to December 2020, 72 patients with memory loss and reduced cognitive functioning as the main complaint and no history of brain infarction were recruited from the Geriatric Department of Zhejiang Hospital. Recruitment strategy included posting flyers and posters in the geriatric ward. During the patient's hospitalization, the geriatric nurse proposed this protocol to the family caregivers of the dementia patient. Interested participants were provided with a flyer included contact information for the research and filled out a contact form.The geriatric nurse confirmed inclusion criteria, and collected the signed informed consent. The control group intervention measures include regular face-to-face follow-up interviews with caregivers to provide education on dementia care knowledge and skills. These measures were conducted every 3 months after the patient's discharge.”

4a-iii) Information giving during recruitment

Information given during recruitment. Specify how participants were briefed for recruitment and in the informed consent procedures (e.g., publish the informed consent documentation as appendix, see also item X26), as this information may have an effect on user self-selection, user expectation and may also bias results.

subitem not at all important

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Does your paper address subitem 4a-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Caregivers meeting the eligibility criteria would be informed of initial details about the study and provided with a subject information sheet. Once potential participants decided to participate, they would be asked to sign the informed consent and be informed of their rights.”

4b) Settings and locations where the data were collected

Does your paper address CONSORT subitem 4b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Due to the in-person meetings restrictions imposed by the Covid-19 pandemic, caregivers participated in two 10-minute online self-assessed surveys through Questionnaire Star at 3 months and 6 months. ”

4b-i) Report if outcomes were (self-)assessed through online questionnaires

Clearly report if outcomes were (self-)assessed through online questionnaires (as common in web-based trials) or otherwise.

subitem not at all important

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Does your paper address subitem 4b-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Due to the in-person meetings restrictions imposed by the Covid-19 pandemic, caregivers participated in two 10-minute online self-assessed surveys through Questionnaire Star at 3 months and 6 months. ”

4b-ii) Report how institutional affiliations are displayed

Report how institutional affiliations are displayed to potential participants [on ehealth media], as affiliations with prestigious hospitals or universities may affect volunteer rates, use, and reactions with regards to an intervention.(Not a required item – describe only if this may bias results)

subitem not at all important

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Does your paper address subitem 4b-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

您的回答

5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered

5-i) Mention names, credential, affiliations of the developers, sponsors, and owners

Mention names, credential, affiliations of the developers, sponsors, and owners [6] (if authors/evaluators are owners or developer of the software, this needs to be declared in a “Conflict of interest” section or mentioned elsewhere in the manuscript).

subitem not at all important

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essential

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Does your paper address subitem 5-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This study was funded by the Zhejiang Provincial Health Commission and no other relevant sponsors were involved.

5-ii) Describe the history/development process

Describe the history/development process of the application and previous formative evaluations (e.g., focus groups, usability testing), as these will have an impact on adoption/use rates and help with interpreting results.

subitem not at all important

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essential

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Does your paper address subitem 5-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Due to the limited length of the article, the history/development process of the application and previous formative evaluations have not been elaborated.

5-iii) Revisions and updating

Revisions and updating. Clearly mention the date and/or version number of the application/intervention (and comparator, if applicable) evaluated, or describe whether the intervention underwent major changes during the evaluation process, or whether the development and/or content was “frozen” during the trial. Describe dynamic components such as news feeds or changing content which may have an impact on the replicability of the intervention (for unexpected events see item 3b).

subitem not at all important

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essential

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Does your paper address subitem 5-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

No major changes occurred during the intervention process, so the above content was not mentioned.

5-iv) Quality assurance methods

Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable.

subitem not at all important

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essential

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Does your paper address subitem 5-iv?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This article did not mention Quality assurance methods.

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used

Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used. Replicability (i.e., other researchers should in principle be able to replicate the study) is a hallmark of scientific reporting.

subitem not at all important

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Does your paper address subitem 5-v?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This information platform has applied for software copyright and has not yet opened its source code.

5-vi) Digital preservation

Digital preservation: Provide the URL of the application, but as the intervention is likely to change or disappear over the course of the years; also make sure the intervention is archived (Internet Archive, webcitation.org, and/or publishing the source code or screenshots/videos alongside the article). As pages behind login screens cannot be archived, consider creating demo pages which are accessible without login.

subitem not at all important

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Does your paper address subitem 5-vi?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This study has saved screenshots of the intervention, but they are not included in the manuscript.

5-vii) Access

Access: Describe how participants accessed the application, in what setting/context, if they had to pay (or were paid) or not, whether they had to be a member of specific group. If known, describe how participants obtained “access to the platform and Internet” [1]. To ensure access for editors/reviewers/readers, consider to provide a “backdoor” login account or demo mode for reviewers/readers to explore the application (also important for archiving purposes, see vi).

subitem not at all important

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Does your paper address subitem 5-vii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“In order to provide users with convenient access to the course at any time and place, the platform was designed to operate through any Internet-enabled device. ”

5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework

Describe mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework [6] used to design them (instructional strategy [1], behaviour change techniques, persuasive features, etc., see e.g., [7, 8] for terminology). This includes an in-depth description of the content (including where it is coming from and who developed it) [1]," whether [and how] it is tailored to individual circumstances and allows users to track their progress and receive feedback" [6]. This also includes a description of communication delivery channels and – if computer-mediated communication is a component – whether communication was synchronous or asynchronous [6]. It also includes information on presentation strategies [1], including page design principles, average amount of text on pages, presence of hyperlinks to other resources, etc. [1].

subitem not at all important

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Does your paper address subitem 5-viii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“In the intervention group, we instructed the informal caregivers of persons with dementia to log in to the platform web page and taught them about the knowledge and skills relevant to home care through the internet. The content on the platform was divided into five different themes, which were: computer cognitive training, language training, reality-oriented therapy, daily life rehabilitation, and care skills training. Computer cognitive training includes concentration (picture-text matching), memory (vocabulary memorization), calculation (simulated shopping), and reaction training (fruit picking). Each training time is 20 minutes, conducted three times a week. Language training aims at improve communication by focusing on vocalization, recognition, and application of words. Reality orientation therapy focuses on presenting patients with facts about the time, date, and current environment. ”

5-ix) Describe use parameters

Describe use parameters (e.g., intended “doses” and optimal timing for use). Clarify what instructions or recommendations were given to the user, e.g., regarding timing, frequency, heaviness of use, if any, or was the intervention used ad libitum.

subitem not at all important

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Does your paper address subitem 5-ix?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Each training time is 20 minutes, conducted three times a week. ”

5-x) Clarify the level of human involvement

Clarify the level of human involvement (care providers or health professionals, also technical assistance) in the e-intervention or as co-intervention (detail number and expertise of professionals involved, if any, as well as “type of assistance offered, the timing and frequency of the support, how it is initiated, and the medium by which the assistance is delivered”. It may be necessary to distinguish between the level of human involvement required for the trial, and the level of human involvement required for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

subitem not at all important

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Does your paper address subitem 5-x?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“The former 4 themes were mainly aimed at improving cognitive function and self-care ability of the care recipient, aiming to alleviate the burden on the caregivers. The latter theme consisted of 18 lessons (270 minutes) aimed at improving caregiver care skills (Table 2). In order to encourage participants to complete the online course training, the online active screen time was calculated. Once the subjects completed at least 80% of the training sessions(216 minutes), they would be posted a book (Long-term Care for Dementia).”

5-xi) Report any prompts/reminders used

Report any prompts/reminders used: Clarify if there were prompts (letters, emails, phone calls, SMS) to use the application, what triggered them, frequency etc. It may be necessary to distinguish between the level of prompts/reminders required for the trial, and the level of prompts/reminders for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

subitem not at all important

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Does your paper address subitem 5-xi? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Once the subjects completed at least 80% of the training sessions(216 minutes), they would be posted a book (Long-term Care for Dementia).”

5-xii) Describe any co-interventions (incl. training/support)

Describe any co-interventions (incl. training/support): Clearly state any interventions that are provided in addition to the targeted eHealth intervention, as ehealth intervention may not be designed as stand-alone intervention. This includes training sessions and support [1]. It may be necessary to distinguish between the level of training required for the trial, and the level of training for a routine application outside of a RCT setting (discuss under item 21 – generalizability.

subitem not at all important

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Does your paper address subitem 5-xii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The intervention measure of the intervention group in this study is eHealth intervention.The control-comparison group would receive an educational booklet on caring for dementia patients provided by the research team. In addition to this education, the control group will also receive face-to-face follow-up guidance and have the option to receive the same intervention after 6 months. The research team's helpline will also be available 24 hours a day to the control group for caregiver assistance.

6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

Does your paper address CONSORT subitem 6a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“To evaluate the effectiveness of the intervention program, researchers used the Neuropsychiatric Inventory-Questionnaire (NPI-Q), the Chinese version of Zarit Caregiver Burden Interview (CZBI), and the Severe Cognitive Impairment Dementia Scale (SCIDS) for assessment before the intervention, 3 months after the intervention, and 6 months after the intervention. ”

6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed

If outcomes were obtained through online questionnaires, describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed [9].

subitem not at all important

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Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

“Due to the in-person meetings restrictions imposed by the Covid-19 pandemic, caregivers participated in two 10-minute online self-assessed surveys through Questionnaire Star at 3 months and 6 months. The primary outcome measures were the Neuropsychiatric Inventory Questionnaire (NPI-Q), the Chinese version of the Zarit Burden Interview(CZBI), and the Sense of Competence in Dementia Care Staff Scale (SCIDS).”

6a-ii) Describe whether and how “use” (including intensity of use/dosage) was defined/measured/monitored

Describe whether and how “use” (including intensity of use/dosage) was defined/measured/monitored (logins, logfile analysis, etc.). Use/adoption metrics are important process outcomes that should be reported in any ehealth trial.

subitem not at all important

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essential

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Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

“The content on the platform was divided into five different themes, which were: computer cognitive training, language training, reality-oriented therapy, daily life rehabilitation, and care skills training. Computer cognitive training includes concentration (picture-text matching), memory (vocabulary memorization), calculation (simulated shopping), and reaction training (fruit picking). Each training time is 20 minutes, conducted three times a week. Language training aims at improve communication by focusing on vocalization, recognition, and application of words. Reality orientation therapy focuses on presenting patients with facts about the time, date, and current environment. ”

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained

Describe whether, how, and when qualitative feedback from participants was obtained (e.g., through emails, feedback forms, interviews, focus groups).

subitem not at all important

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essential

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Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

This study did not collect qualitative feedback data from participants.

6b) Any changes to trial outcomes after the trial commenced, with reasons

Does your paper address CONSORT subitem 6b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“According to the results of repeated measures analysis of variance, as shown in Table 3, it was found that intervention and time had significant statistical effects on the NPI-Q, CZBI, and SCIDS ($P<0.05$), and the significant interaction effects of group x time in primary outcome indicators were also found ($P<0.05$).”

7a) How sample size was determined

NPT: When applicable, details of whether and how the clustering by care provides or centers was addressed

7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size

Describe whether and how expected attrition was taken into account when calculating the sample size.

subitem not at all important

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essential

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Does your paper address subitem 7a-i?

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Taking into account a potential 10% loss of samples during the study, the final sample size was determined to be 36 individuals per group.”

7b) When applicable, explanation of any interim analyses and stopping guidelines

Does your paper address CONSORT subitem 7b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Categorical variables were expressed as frequencies and proportions and compared using a chi-square test between groups. In repeated measures analysis of variance, when the assumption of sphericity was violated (evaluated using Mauchly's test), the degrees of freedom value for testing the F-ratio was adjusted using the Greenhouse-Geisser correction. If there was no interaction effect between time and treatment factors in the repeated measures ANOVA results, the main effects test was used to evaluate the treatment effect. If there was an interaction effect, separate analyses were performed: the within-group effect was evaluated using a one-way repeated measures ANOVA, and the between-group effect was evaluated using a multivariate ANOVA. Bonferroni correction was used for post-hoc multiple pairwise comparisons.”

8a) Method used to generate the random allocation sequence

NPT: When applicable, how care providers were allocated to each trial group

Does your paper address CONSORT subitem 8a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Participants were randomly allocated on a 1:1 ratio assigned to either the intervention or a waiting list control group after baseline assessment. Randomization was carried out using a random number generator. ”

8b) Type of randomisation; details of any restriction (such as blocking and block size)

Does your paper address CONSORT subitem 8b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Participants were randomly allocated on a 1:1 ratio assigned to either the intervention or a waiting list control group after baseline assessment. Randomization was carried out using a random number generator.”

9) Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

Does your paper address CONSORT subitem 9? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Participants were randomly allocated on a 1:1 ratio assigned to either the intervention or a waiting list control group after baseline assessment. Randomization was carried out using a random number generator.”

10) Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

Does your paper address CONSORT subitem 10? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

”During the interviews, trained interviewers were blinded to the group allocations. ”

11a) If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how

NPT: Whether or not administering co-interventions were blinded to group assignment

11a-i) Specify who was blinded, and who wasn't

Specify who was blinded, and who wasn't. Usually, in web-based trials it is not possible to blind the participants [1, 3] (this should be clearly acknowledged), but it may be possible to blind outcome assessors, those doing data analysis or those administering co-interventions (if any).

subitem not at all important

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Does your paper address subitem 11a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Caregivers meeting the eligibility criteria would be informed of initial details about the study and provided with a subject information sheet. Once potential participants decided to participate, they would be asked to sign the informed consent and be informed of their rights. Baseline information was collected by trained interviewers from participants through completing standardized questionnaires. During the interviews, trained interviewers were blinded to the group allocations. Participants were randomly allocated on a 1:1 ratio assigned to either the intervention or a waiting list control group after baseline assessment. Randomization was carried out using a random number generator. "

11a-ii) Discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”

Informed consent procedures (4a-ii) can create biases and certain expectations - discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”.

subitem not at all important

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Does your paper address subitem 11a-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

”Caregivers meeting the eligibility criteria would be informed of initial details about the study and provided with a subject information sheet. Once potential participants decided to participate, they would be asked to sign the informed consent and be informed of their rights. Baseline information was collected by trained interviewers from participants through completing standardized questionnaires. ”

11b) If relevant, description of the similarity of interventions

(this item is usually not relevant for ehealth trials as it refers to similarity of a placebo or sham intervention to a active medication/intervention)

Does your paper address CONSORT subitem 11b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“In the intervention group, we instructed the informal caregivers of persons with dementia to log in to the platform web page and taught them about the knowledge and skills relevant to home care through the internet.”“The control-comparison group would receive an educational booklet on caring for dementia patients provided by the research team. In addition to this education, the control group will also receive face-to-face follow-up guidance and have the option to receive the same intervention after 6 months. The research team's helpline will also be available 24 hours a day to the control group for caregiver assistance. ”

12a) Statistical methods used to compare groups for primary and secondary outcomes

NPT: When applicable, details of whether and how the clustering by care providers or centers was addressed

Does your paper address CONSORT subitem 12a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Data were tested using normal distribution or variance homogeneity analysis before statistical analysis using SPSS20.0 statistical software. Continuous variables that followed a normal distribution were expressed as mean and standard deviation and were compared using an independent t-test between the two groups. Categorical variables were expressed as frequencies and proportions and compared using a chi-square test between groups. In repeated measures analysis of variance, when the assumption of sphericity was violated (evaluated using Mauchly's test), the degrees of freedom value for testing the F-ratio was adjusted using the Greenhouse-Geisser correction. If there was no interaction effect between time and treatment factors in the repeated measures ANOVA results, the main effects test was used to evaluate the treatment effect. If there was an interaction effect, separate analyses were performed: the within-group effect was evaluated using a one-way repeated measures ANOVA, and the between-group effect was evaluated using a multivariate ANOVA. Bonferroni correction was used for post-hoc multiple pairwise comparisons.”

12a-i) Imputation techniques to deal with attrition / missing values

Imputation techniques to deal with attrition / missing values: Not all participants will use the intervention/comparator as intended and attrition is typically high in ehealth trials. Specify how participants who did not use the application or dropped out from the trial were treated in the statistical analysis (a complete case analysis is strongly discouraged, and simple imputation techniques such as LOCF may also be problematic [4]).

subitem not at all important

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Does your paper address subitem 12a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“In the follow-up period, 3 patients in the intervention group and the control group were lost to follow-up, respectively. In the intervention group, two caregivers accompanied the dementia patients as they relocated to a different city, and another caregiver returned to her hometown after the dementia patient was admitted to a nursing home. In the control group, one caregiver accompanied the dementia people emergency admission who suffered a fracture, another caregiver failed to continue to contact after repeated appointments, and one caregiver accompanied patient to a nursing home (Fig.1).
”

12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses

Does your paper address CONSORT subitem 12b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“This manuscript did not perform subgroup analysis and adjusted analysis.”

X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item)

X26-i) Comment on ethics committee approval

subitem not at all important

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Does your paper address subitem X26-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“All procedures were in accordance with the Helsinki Declaration and the study was approved by the Ethics Review Committee of ** Hospital (REDACTED). ”

x26-ii) Outline informed consent procedures

Outline informed consent procedures e.g., if consent was obtained offline or online (how? Checkbox, etc.?), and what information was provided (see 4a-ii). See [6] for some items to be included in informed consent documents.

subitem not at all important

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Does your paper address subitem X26-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Interested participants were provided with a flyer included contact information for the research and filled out a contact form.The geriatric nurse confirmed inclusion criteria, and collected the signed informed consent. ”

X26-iii) Safety and security procedures

Safety and security procedures, incl. privacy considerations, and any steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline)

subitem not at all important

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Does your paper address subitem X26-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“The research team's helpline will also be available 24 hours a day to the control group for caregiver assistance. ”

RESULTS

13a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

NPT: The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider in each center

Does your paper address CONSORT subitem 13a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

”Baseline information was collected by trained interviewers from participants through completing standardized questionnaires. During the interviews, trained interviewers were blinded to the group allocations. Participants were randomly allocated on a 1:1 ratio assigned to either the intervention or a waiting list control group after baseline assessment. Randomization was carried out using a random number generator. ”

13b) For each group, losses and exclusions after randomisation, together with reasons

Does your paper address CONSORT subitem 13b? (NOTE: Preferably, this is shown in a CONSORT flow diagram) *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“In the follow-up period, 3 patients in the intervention group and the control group were lost to follow-up, respectively. In the intervention group, two caregivers accompanied the dementia patients as they relocated to a different city, and another caregiver returned to her hometown after the dementia patient was admitted to a nursing home. In the control group, one caregiver accompanied the dementia people emergency admission who suffered a fracture, another caregiver failed to continue to contact after repeated appointments, and one caregiver accompanied patient to a nursing home (Fig.1). ”

13b-i) Attrition diagram

Strongly recommended: An attrition diagram (e.g., proportion of participants still logging in or using the intervention/comparator in each group plotted over time, similar to a survival curve) or other figures or tables demonstrating usage/dose/engagement.

subitem not at all important

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essential

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Does your paper address subitem 13b-i?

Copy and paste relevant sections from the manuscript or cite the figure number if applicable (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Fig.1 flowchart of study participants”

14a) Dates defining the periods of recruitment and follow-up

Does your paper address CONSORT subitem 14a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Between July 2019 and December 2020, 72 informal primary caregivers of people with dementia of all subtypes and stages were recruited via Zhejiang Provincial Geriatric Medical Center .”

14a-i) Indicate if critical “secular events” fell into the study period

Indicate if critical “secular events” fell into the study period, e.g., significant changes in Internet resources available or “changes in computer hardware or Internet delivery resources”

subitem not at all important

- 1 ○
- 2 ◉
- 3 ○
- 4 ○
- 5 ○

essential

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Does your paper address subitem 14a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“There was no critical “secular events” fell into the study period.”

14b) Why the trial ended or was stopped (early)

Does your paper address CONSORT subitem 14b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“By providing online knowledge and skills training through the internet, the preliminary trial showed that the average CZBI has decreased by 12.5. Using PASS software (version 16.0), the minimum sample size for each group was identified as 27. ”

15) A table showing baseline demographic and clinical characteristics for each group

NPT: When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group

Does your paper address CONSORT subitem 15? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“The patients in the control and intervention groups were comparable in terms of their baseline data such as sex, education level, marital status, age, BMI, number of children, number of diseases, and number of long-term medications (Table 1). ”

15-i) Report demographics associated with digital divide issues

In ehealth trials it is particularly important to report demographics associated with digital divide issues, such as age, education, gender, social-economic status, computer/Internet/ehealth literacy of the participants, if known.

subitem not at all important

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- 5 ◉

essential

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Does your paper address subitem 15-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“The patients in the control and intervention groups were comparable in terms of their baseline data such as sex, education level, marital status, age, BMI, number of children, number of diseases, and number of long-term medications (Table 1). ”

16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

16-i) Report multiple “denominators” and provide definitions

Report multiple “denominators” and provide definitions: Report N’s (and effect sizes) “across a range of study participation [and use] thresholds” [1], e.g., N exposed, N consented, N used more than x times, N used more than y weeks, N participants “used” the intervention/comparator at specific pre-defined time points of interest (in absolute and relative numbers per group). Always clearly define “use” of the intervention.

subitem not at all important

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essential

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Does your paper address subitem 16-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Please see Tables 3, 4, and 5 for details.”

16-ii) Primary analysis should be intent-to-treat

Primary analysis should be intent-to-treat, secondary analyses could include comparing only “users”, with the appropriate caveats that this is no longer a randomized sample (see 18-i).

subitem not at all important

- 1 ○
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essential

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Does your paper address subitem 16-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“In repeated measures analysis of variance, when the assumption of sphericity was violated (evaluated using Mauchly's test), the degrees of freedom value for testing the F-ratio was adjusted using the Greenhouse-Geisser correction. If there was no interaction effect between time and treatment factors in the repeated measures ANOVA results, the main effects test was used to evaluate the treatment effect. If there was an interaction effect, separate analyses were performed: the within-group effect was evaluated using a one-way repeated measures ANOVA, and the between-group effect was evaluated using a multivariate ANOVA. Bonferroni correction was used for post-hoc multiple pairwise comparisons.”

17a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)

Does your paper address CONSORT subitem 17a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Between July 2019 and December 2020, a total of 66 patients successfully completed the intervention and follow-up. After 6 months of intervention, the NPI-Q score of the intervention group was 3.18±3.81, the ZBI score was 10.97±5.43, and the SCIDS score was 71.88±4.78. The NPI-Q score of the control group was 8.09±8.52, the ZBI score was 30.30±13.05, and the SCIDS score was 50.12±9.10. There were statistically significant differences in NPI-Q (P=0.004), ZBI (P<0.001), and SCIDS scores (P<0.001) between the intervention group and the control group. Repeated measures analysis of variance showed that compared with before the intervention, there were statistically significant differences in ZBI (P<0.001) and SCIDS (P<0.001) scores three months after the intervention, while the difference in NPI-Q (P=0.105) scores was not significant. The total scores of NPI-Q (P<0.001), ZBI (P<0.001), and SCIDS (P<0.001) were significantly improved six months after the intervention. In addition, the results of covariance analysis showed that after excluding the time effect, the online training intervention significantly reduced the NPI-Q score (-2.79(-4.38, -1.19), P<0.001) of dementia patients and the ZBI score (-13.52(-15.87, -11.16), P<0.001) of caregivers, while increasing the SCIDS score (12.24(9.02, 15.47), P<0.001).”

17a-i) Presentation of process outcomes such as metrics of use and intensity of use

In addition to primary/secondary (clinical) outcomes, the presentation of process outcomes such as metrics of use and intensity of use (dose, exposure) and their operational definitions is critical. This does not only refer to metrics of attrition (13-b) (often a binary variable), but also to more continuous exposure metrics such as “average session length”. These must be accompanied by a technical description how a metric like a “session” is defined (e.g., timeout after idle time) [1] (report under item 6a).

subitem not at all important

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essential

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Does your paper address subitem 17a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“The Neuropsychiatric Inventory Questionnaire (NPI-Q) [15] is an observer rating scale was used to evaluate participants’ neuropsychiatric symptoms across 12 different areas, including delusions, hallucinations, agitation/aggression, depression/dysphoria, anxiety, elation/euphoria, apathy/indifference, disinhibition, irritability/emotional lability, aberrant motor behaviors, nighttime behavioral disturbances, and appetite/eating disturbances. Each symptom was evaluated with a basic screening question (responded to with “present” or “absent”). If a positive answer is given to the screening question, a more detailed exploration of specific areas will be conducted. The neurobehavioral manifestations within a domain are collectively rated by caregivers based on frequency (1 to 4) and severity (1 to 3), resulting in a composite domain score (frequency x severity), with higher scores indicating greater severity of symptoms. The total score of NPI is defined as the sum of scores from 12 symptom evaluations, with a maximum score of 144. The Cronbach's α coefficient of the NPI-Q was 0.82, and the test-retest coefficients ranged from 0.66 to 0.98 ($p < 0.001$) [16].
The caregiver burden was measured using the Chinese version of the Zarit Burden Interview(CZBI) [17]. CZBI consists of 22 items that require a Likert-type response ranging from O (never) to 4 (almost always), with a total score range from 0 to 88. A higher score indicates an increased caregiver burden. The internal consistency value, established by Cronbach's alpha coefficient, was 0.89 and the intraclass correlation coefficient for test-retest reliability of the total score was 0.88.
Sense of Competence in Dementia Care Staff Scale (SCIDS) is designed to evaluate the level of competency among caregivers in providing care for individuals with dementia [18]. The scale consists of 17 items across four subscales: professionalism, relationship-building, care challenges, and sustaining personhood. SCIDS has acceptable to good internal consistency (Cronbach's α=0.91) and moderate to substantial test-retest reliability (0.74). The total score of the scale ranges from 17 to 68 points, with higher scores indicating that staff members have better conscious dementia care abilities.

17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended

Does your paper address CONSORT subitem 17b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This manuscript does not contain relevant content.

18) Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory

Does your paper address CONSORT subitem 18? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This manuscript does not contain relevant content.

18-i) Subgroup analysis of comparing only users

A subgroup analysis of comparing only users is not uncommon in ehealth trials, but if done, it must be stressed that this is a self-selected sample and no longer an unbiased sample from a randomized trial (see 16-iii).

subitem not at all important

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essential

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Does your paper address subitem 18-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This manuscript does not contain relevant content.

19) All important harms or unintended effects in each group

(for specific guidance see CONSORT for harms)

Does your paper address CONSORT subitem 19? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“In the follow-up period, 3 patients in the intervention group and the control group were lost to follow-up, respectively. In the intervention group, two caregivers accompanied the dementia patients as they relocated to a different city, and another caregiver returned to her hometown after the dementia patient was admitted to a nursing home. In the control group, one caregiver accompanied the dementia people emergency admission who suffered a fracture, another caregiver failed to continue to contact after repeated appointments, and one caregiver accompanied patient to a nursing home (Fig.1).“

19-i) Include privacy breaches, technical problems

Include privacy breaches, technical problems. This does not only include physical “harm” to participants, but also incidents such as perceived or real privacy breaches [1], technical problems, and other unexpected/unintended incidents. “Unintended effects” also includes unintended positive effects [2].

subitem not at all important

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- 5 ○

essential

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Does your paper address subitem 19-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Recruitment strategy included posting flyers and posters in the geriatric ward. During the patient's hospitalization, the geriatric nurse proposed this protocol to the family caregivers of the dementia patient. Interested participants were provided with a flyer included contact information for the research and filled out a contact form.The geriatric nurse confirmed inclusion criteria, and collected the signed informed consent. ”

19-ii) Include qualitative feedback from participants or observations from staff/researchers

Include qualitative feedback from participants or observations from staff/researchers, if available, on strengths and shortcomings of the application, especially if they point to unintended/unexpected effects or uses. This includes (if available) reasons for why people did or did not use the application as intended by the developers.

subitem not at all important

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essential

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Does your paper address subitem 19-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This manuscript does not contain relevant content.

DISCUSSION

22) Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

NPT: In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group

22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)

Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use).

subitem not at all important

- 1 ○
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- 5 ◉

essential

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Does your paper address subitem 22-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“As a cost-effective, convenient, and accessible intervention, web-based solutions have emerged to support informal caregivers. The advantage of online support training lies in breaking the limitations of time and space, providing a feasible solution for the popularization of support services. During the COVID-19 pandemic, our research project provided digital resources through online support and training to informal caregivers of persons with dementia patients, which improved the caregivers' skills and alleviated their burden.”

22-ii) Highlight unanswered new questions, suggest future research

Highlight unanswered new questions, suggest future research.

subitem not at all important

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5 ◉

essential

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Does your paper address subitem 22-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“ During the COVID-19 pandemic, our research project provided digital resources through online support and training to informal caregivers of persons with dementia patients, which improved the caregivers' skills and alleviated their burden.”

20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses

20-i) Typical limitations in ehealth trials

Typical limitations in ehealth trials: Participants in ehealth trials are rarely blinded. Ehealth trials often look at a multiplicity of outcomes, increasing risk for a Type I error. Discuss biases due to non-use of the intervention/usability issues, biases through informed consent procedures, unexpected events.

subitem not at all important

- 1 ○
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- 4 ◉
- 5 ○

essential

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Does your paper address subitem 20-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Third, we measured outcomes and exposures using self-reported questionnaires, so reporting errors were possible. Despite these limitations, our plan is still noteworthy because it is one of the few online interventions that has a significant impact on fostering positive emotions towards caregiving and reducing the burden on informal caregivers of persons with dementia patients. ”

21) Generalisability (external validity, applicability) of the trial findings

NPT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

21-i) Generalizability to other populations

Generalizability to other populations: In particular, discuss generalizability to a general Internet population, outside of a RCT setting, and general patient population, including applicability of the study results for other organizations

subitem not at all important

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essential

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Does your paper address subitem 21-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“ As a cost-effective, convenient, and accessible intervention, web-based solutions have emerged to support informal caregivers. The advantage of online support training lies in breaking the limitations of time and space, providing a feasible solution for the popularization of support services. ”

21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting

Discuss if there were elements in the RCT that would be different in a routine application setting (e.g., prompts/reminders, more human involvement, training sessions or other co-interventions) and what impact the omission of these elements could have on use, adoption, or outcomes if the intervention is applied outside of a RCT setting.

subitem not at all important

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essential

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Does your paper address subitem 21-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"This study offered a solution to the challenges faced by informal caregivers by providing them with training through online programs. They would gain knowledge and skills to adjust their caregiving schedules flexibly to accommodate the needs of individuals with dementia. This approach not only empowered informal caregivers but also optimized the use of home care resources, making care provision more effective."

OTHER INFORMATION

23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Chinese Clinical Trial Registe ChiCTR2200057858; https://www.chictr.org.cn/showproj.html?proj=136442”

24) Where the full trial protocol can be accessed, if available

Does your paper address CONSORT subitem 24? *

Cite a Multimedia Appendix, other reference, or copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Chinese Clinical Trial Registe ChiCTR2200057858; https://www.chictr.org.cn/showproj.html?proj=136442”

25) Sources of funding and other support (such as supply of drugs), role of funders

Does your paper address CONSORT subitem 25? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“This work was supported by grants from the National Key Research and Development Program of China (program number:2019YFE0113100), Zhejiang Provincial Medicine and Health Technology Project (grant number 2019KY003) and Zhejiang Hospital 3060 Excellent Young Talents Training Project.”

X27) Conflicts of Interest (not a CONSORT item)

X27-i) State the relation of the study team towards the system being evaluated

In addition to the usual declaration of interests (financial or otherwise), also state the relation of the study team towards the system being evaluated, i.e., state if the authors/evaluators are distinct from or identical with the developers/sponsors of the intervention.

subitem not at all important

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essential

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Does your paper address subitem X27-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

“Authors' contributions Yanhong Xie, Hong Hong were the major contributor in writing and revising the manuscript. Yanhong Xie and Shanshan Shen analyzed and interpreted the patient data regarding intervention and revised the manuscript. HuiLan Guan and JingMei Zhang performed the scales assessment and data collection of all the patients. YanHong Xie and WanQi Yu performed the data analysis. All authors read and approved the final manuscript.”

About the CONSORT EHEALTH checklist

As a result of using this checklist, did you make changes in your manuscript? *

- ○ yes, major changes
- ○ yes, minor changes
- ◉ no

What were the most important changes you made as a result of using this checklist?

您的回答

How much time did you spend on going through the checklist INCLUDING making changes in your manuscript *

It took me about 3 days to check the list, including revising my manuscript.

As a result of using this checklist, do you think your manuscript has improved? *

- ◉ yes
- ○ no
- ○ 其他:

Would you like to become involved in the CONSORT EHEALTH group?

This would involve for example becoming involved in participating in a workshop and writing an "Explanation and Elaboration" document

- ○ yes
- ◉ no
- ○ 其他:

清除所选内容

Any other comments or questions on CONSORT EHEALTH

您的回答

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