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

The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating webbased 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):

Evsenbach 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

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Title of your manuscript *	
Provide the (draft) title of you	ur manuscript.
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Article Preparation Status , At which stage in your article	/Stage * e preparation are you currently (at the time you fill in this form)
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TITLE AND ABSTRACT

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

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

yes	
Other:	

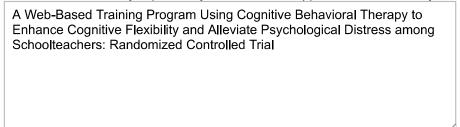
1a-i) Identify the mode of delivery in the title

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.

	1	2	3	4	5	
subitem not at all important						essential

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



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").



Does your paper address subitem 1a-ii?

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)

Does your paper address subitem 1b-i? *

8/7/2017

This study was conducted in a random controlled design covering public elementary schoolteachers. Teachers allocated to the intervention group received 120 min of group education and completed homework using a web-based CBT program that lasted 3 months. The items of outcome evaluation were cognitive flexibility and subjective distress, and the efficacy of intervention was evaluated at 3 months after intervention.

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)

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subitem not at all important	\bigcirc				\bigcirc	essential

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

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)



Does your paper address subitem 1b-iii?

8/7/2017

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)



Does your paper address subitem 2a-i? *

It is known that schoolteachers are faced with much stress. It is therefore important to seek measures to enhance the stress management skills of schoolteachers. Each schoolteacher in Japan bears the weight of various responsibilities besides lessons in class, including moral guidance, giving counsel to parents, being an advisor to school clubs after class. participating in activities to enhance educational effects, and preparation of reports. Therefore, teachers often feel distress about various areas, and thus, the mental health of Japanese schoolteachers is lower than that of general workers [1,2]. In addition, the number of Japanese public schoolteachers who are on leave of absence for mental illness is showing an almost consistent upward trend, such that schoolteachers on leave of absence for mental illness accounts for more than 60% of all schoolteachers on leave of absence for any illness [3]. Because poor mental health of teachers affects not only teachers themselves, but also their students, this is a socially important problem. Previous studies that examined the relationship between poor mental health or burnout of teachers and various factors have identified less years of experience as a teacher and young age [4-7], insufficient social support [5, 8,9], and stress management skills of the individual [10-12] as contributing factors. In particular, a study of young and inexperienced teachers revealed that stress management skills of the individual, rather than job-related stressors, were significantly correlated with mental health [13]. Therefore, it is presumed that policies for not only decreasing stressors, but also enhancing stress management skills of teachers are necessary to improve the mental health of schoolteachers.

A preceding study reported that cognitive behavioral therapy (CBT) is useful for enhancing stress management skills of workers [14]. CBT enhances cognitive flexibility, thereby challenging and replacing maladaptive thoughts with more balanced and adaptive thinking [15,16]. According to Dennis et al., cognitive flexibility reflects the following three aspects: the tendency to perceive difficult situations as controllable, the ability to perceive multiple alternative explanations for life occurrences and human behavior, and the ability to generate multiple alternative solutions to difficult situations [17]. Previous studies in healthy subjects have found that individual differences in cognitive flexibility significantly effectively predicted good performance on tasks that required carefulness [18], and cognitive flexibility was involved in fluent creativity and new ideas [19]. It has also been reported that persons with a high feeling of happiness have high cognitive flexibility, and executed tasks of higher creativity [19]. Therefore, CBT may improve the performance of schoolteachers as well as their stress management skills, by improving their cognitive flexibility.

Low-intensity CBT, a program to provide the essence of CBT using simple measures including group education, use of the Internet, and books is now spreading to utilize CBT in a wide range of scenarios beyond clinical treatment. It is also reported that stress management education using CBT performed on the Internet (web-based CBT) alleviated the distresses of general workers and enhanced their cognitive flexibility [20,21]. However, there has been no study that examined whether training programs of schoolteachers using low-intensity CBT would enhance their cognitive flexibility and be effective for reducing their stress.

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 appropriate), 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.

subitem not at all important \(\cap \) \(\cap \) \(\cap \) essential

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

Low-intensity CBT, a program to provide the essence of CBT using simple measures including group education, use of the Internet, and books is now spreading to utilize CBT in a wide range of scenarios beyond clinical treatment. It is also reported that stress management education using CBT performed on the Internet (web-based CBT) alleviated the distresses of general workers and enhanced their cognitive flexibility [20,21]. However, there has been no study that examined whether training programs of schoolteachers using low-intensity CBT would enhance their cognitive flexibility and be effective for reducing their stress.

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

In this regard, this study provided schoolteachers with simple stress management training using a web-based CBT program that allowed each of them to complete CBT homework independently, and investigated whether the training would contribute to the enhancement of cognitive flexibility and reduction of stress among teachers.

METHODS

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

Does your paper address CONSORT subitem 3a? *

Randomized Control Trial	
	_4

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

None	
	- /·

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].

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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

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

This study included 241 schoolteachers serving in public elementary schools in Sagamihara City in Kanagawa, Japan, who were in the fifth year of their career and were prospective participants in a mental health-related training program in 2014

4a-i) Com	puter /	Internet	literacy
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Computer / Interne	t literacy is often	an implicit	"de facto"	eligibility	criterion	- this should	be explicitly
clarified							

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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

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 quasianonymous 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.

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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

This study included 241 schoolteachers serving in public elementary schools in Sagamihara City in Kanagawa, Japan, who were in the fifth year of their career and were prospective participants in a mental health-related training program in 2014

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.

1 2 3 4 5 subitem not at all important \(\cap \) \(\cap \) \(\cap \) essential

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
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
This study included 241 schoolteachers serving in public elementary schools in Sagamihara City in Kanagawa, Japan
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.
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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 major briefly explain why the item is not applicable (relevant for your study).
None. First questionnaires was done in face to face. Second questionnaires was done by postal mail.

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)

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Describe the history/de	y/development process opment process of the application and previous formative evaluations (e.g. is these will have an impact on adoption/use rates and help with interpreting	
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Does your	paper	address	subitem	5-ii?
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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

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).

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

5-iv) Quality assurance methods

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

Does your paper address subitem 5-iv?

8/7/2017

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).

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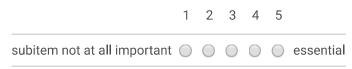
Does your paper address subitem 5-vii? *

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

The homework using the web-based CBT program lasted for 3 months after the end of group education. The web-based CBT program used "Mind Skill Up Training"[23]. This website, developed by a specialist in CBT, is designed for trainees to practice cognitive restructuring by themselves using the guide. This site is open to the public for use with a charge. Each participant in this study was given an ID and password by the investigator to access the website. Self-learning on the web was feasible in the workplace or at home as long as a proper IT environment was in place; the place of self-learning varied according to the convenience of the participant. During the homework implementation period, an e-mail from a health nurse who was one of the investigators of this study was delivered to participants 6 times to provide information on CBT and urge them to do homework. Implementation of at least 3 sessions of homework was encouraged.

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].



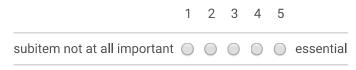
Does your paper address subitem 5-viii? *

CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form
The intervention consisted of one session of group education about CBT (lecture on CBT, group session using a column table), homework using the web-based CBT program for the subsequent 3 months, and 6 e-mails sent during the self-learning period to stimulate the implementation of the web-based CBT program (Table 1).
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.
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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
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).
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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

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).



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

The homework using the web-based CBT program lasted for 3 months after the end of group education. The web-based CBT program used "Mind Skill Up Training"[23]. This website, developed by a specialist in CBT, is designed for trainees to practice cognitive restructuring by themselves using the guide. This site is open to the public for use with a charge. Each participant in this study was given an ID and password by the investigator to access the website. Self-learning on the web was feasible in the workplace or at home as long as a proper IT environment was in place; the place of self-learning varied according to the convenience of the participant. During the homework implementation period, an e-mail from a health nurse who was one of the investigators of this study was delivered to participants 6 times to provide information on CBT and urge them to do homework. Implementation of at least 3 sessions of homework was encouraged.

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.



Does your paper address subitem 5-xii? *

A specialist in CBT took charge of the group education. One session of group education consisted of part 1 and part 2, taking 120 min in total (Table 1).

The homework using the web-based CBT program lasted for 3 months after the end of group education (Table 1).

The web-based CBT program used "Mind Skill Up Training"[23]. This website, developed by a specialist in CBT, is designed for trainees to practice cognitive restructuring by themselves using the guide. This site is open to the public for use with a charge. Each participant in this study was given an ID and password by the investigator to access the website. Self-learning on the web was feasible in the workplace or at home as long as a proper IT environment was in place; the place of self-learning varied according to the convenience of the participant. During the homework implementation period, an e-mail from a health nurse who was one of the investigators of this study was delivered to participants 6 times to provide information on CBT and urge them to do homework. Implementation of at least 3 sessions of homework was encouraged.

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

The outcomes were cognitive flexibility and degree of subjective distress. Questions about these items were prepared, and evaluation was performed at baseline and 3 months after the end of the homework period, using selfadministered questionnaires. Cognitive flexibility was evaluated in terms of the following three points proposed by Dennis et al.: "I have a tendency to perceive difficult situations as controllable," "I can perceive multiple alternative explanations for difficult situations," and "I can generate multiple alternative solutions to difficult situations." These items were rated according to 5 grades (1: not at all-5: completely applicable." Subjective distress was examined by the question "How much do you perceive stress at work?" and rated according to 10 grades (1: not at all-10: very strongly). In addition, participants were examined for their base attributes including depression in terms of the Beck depression inventory (BDI), which is an index with established reliability and validity developed by Beck et al. [24], degree of mental health based on the K-6, which is a screening questionnaire with established validity and reliability developed by Kessler et al. and comprising 6 items for screening the state of depression and mood or anxiety disorders in the general population [25], overtime hours, hours of sleep, marital status, drinking habits, exercise habits, and history of seeking medical advice for mental illness as well as age, gender, and employee number.

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

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Describe whether and how logins, logfile analysis, etc eported in any ehealth tria	:.). Us												
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8/7/2017

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

None		

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

An independent researcher who had no direct contact with the participants used computer-generated randomization with a 1:1 ratio and block size of 6. No stratification was performed and evaluators were masked. Owing to the nature of the intervention, participants were informed of their allocation status.

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

An independent researcher who had no direct contact with the participants used computer-generated randomization with a 1:1 ratio and block size of 6. No stratification was performed and evaluators were masked. Owing to the nature of the intervention, participants were informed of their allocation status.

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



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

An independent researcher who had no direct contact with the participants.	

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).

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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
An independent researcher who had no direct contact with the participants.
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".
1 2 3 4 5
subitem not at all important O O O essential
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
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 None

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

A generalized linear model was used for estimation, based on an intention-to-treat (ITT) analysis. To satisfy the ITT requirement that analyses be conducted for all participants, a multiple imputation (MI) method was used on the assumption that data could be considered missing at random. MI allows for uncertainty caused by missing data by generating several different plausible imputed data sets using a set of external covariates and appropriately combining results obtained from each [26,27].

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]).

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

A generalized linear model was used for estimation, based on an intention-to-treat (ITT) analysis. To satisfy the ITT requirement that analyses be conducted for all participants, a multiple imputation (MI) method was used on the assumption that data could be considered missing at random. MI allows for uncertainty caused by missing data by generating several different plausible imputed data sets using a set of external covariates and appropriately combining results obtained from each [26,27].

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

Does your paper address CONSORT subitem 12b? *

To analyze baseline characteristics of the study participants, a test was used for numerical variables and a $\chi 2$ test for categorical variables. Statistical significance was set at P<.05. IBM SPSS 22 and IBM SPSS Missing Values 22 (SPSS Inc., Chicago, IL, USA) were used for statistical analyses.

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

X26-i) Comment on ethics committee approval



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

The study protocol was approved by the Ethics Committee of the School of Allied Health Sciences at Kitasato University. Reporting of methods and results of this study are based on the CONSORT-EHEALTH guidelines [22].

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.



Does your paper address subitem X26-ii?

All potential study participants were instructed orally or in writing by the investigator prior to the beginning of the study that they could discontinue participation at any time if problems were caused by the intervention, and that this study was to be conducted by an organization independent of the board of education and would have no influence on personnel evaluation. Only the persons who gave consent to this study after this explanation were included in this study. They were also instructed that participation in the study should be completely of their own volition, and that not participating in the study would cause no disadvantages.

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)

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

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? *

CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form
Figure 1
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 CONSOR
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
Figure 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.
1 2 3 4 5
subitem not at all important O O O essential
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

14a) Dates defining the periods of recruitment and followup

Does v	vour	paper	address	CONSORT	subitem	14a? *	k
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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

From the board education of Sagamihara City for the mental health training in 2014 to 3 months.	

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"

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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

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

None			

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

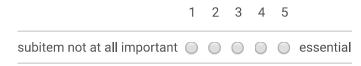
Does your paper address CONSORT subitem 15? *

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



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.



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

Table 2	
	ā.

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.

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CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form
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
Table 2, Table 3.
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).
1 2 3 4 5
subitem not at all important 🔘 🔘 🔘 essential
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
17a) For each primary and secondary outcome, results for
each group, and the estimated effect size and its precision
(such as 95% confidence interval)
(Section 1997)
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

Table 3		

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).

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17b) For binal and relative e	-					solute

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

None		

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? *

	CONSORT-ENEALTH (V 1.0.1) - Submission/Publication Form
None	
	s of comparing only users omparing only users is not uncommon in ehealth trials, but if done, it must be
stressed that this is a 16-iii).	f-selected sample and no longer an unbiased sample from a randomized trial
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ndicate direct quotes	ss subitem 18-i? sections from the manuscript (include quotes in quotation marks "like this" to om your manuscript), or elaborate on this item by providing additional informat xplain why the item is not applicable/relevant for your study

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

None. No occurrence of important harms or unintended effects was observed.	

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].

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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).

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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

In addition, this study used some mechanisms to maintain motivation for training. Because CBT intervention in healthy subjects may be associated with low motivation for intervention, unlike patients who seek treatment, we emphasized to participants that training based on the principles of CBT in group education would be useful for coping with work stress and for improvement of productivity [39,40]. It has also been reported that reminding increases the implementation rate when CBT is performed on the Internet [41,42]. Therefore, 6 e-mails from a health nurse to urge completion of homework were designed to be delivered to each participant during the 3 months of homework. Furthermore, to raise the implementation rate, group education was provided during working hours, and homework was made feasible at home as well as in the workplace. Although the implementation rate of homework was not determined in this study, we presume that these mechanisms contributed to improvement of the implementation rate of homework.

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

Highlight unanswered new questions, suggest future research.

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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

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 \(\cap \) \(\cap \) \(\cap \) essential

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

The limitations of this study were as follows:

- 1. Evaluation indices were our original inquiry items. Although validated scales that evaluate psychological stress are present, and a limited number of scales for cognitive flexibility have been proposed, all these scales include many items. For this study, we chose to use simple questionnaire scales at the stage of study planning. Because of this, a one-item scale was used for each outcome.
- 2. Participants were limited to teachers in a city who were in the fifth year of their career. To increase the general validity of this study, this issue should be studied in a randomized controlled trial (RCT) design under wider conditions
- 3. Homework implementation status was not evaluated. This was aimed at reducing burden on the participants. However, because homework is considered to play an important part in CBT, it would have been desirable if we had analyzed in detail how often the participants performed the simplified CBT program and whether and how closely the number of implemented homework sessions was correlated with the effect of CBT.
- 4. Evaluation of outcomes was completed only at 3 months after the completion of intervention. The decision to do this was made at the stage of study planning to reduce burden on the participants. However, longer follow-up would have been desirable, considering that the amount of work varies according to the time of year, and for the purpose of examining the long-term effect.

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

Does your paper address subitem 21-i?

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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.
1 2 3 4 5
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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
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
Not required for pilot study.

8/7/2017

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

Does your paper	r 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

None		
		/

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

None		

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.

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Does your paper address subitem X27-i?

None declared.	

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As a result of using this ch	ecklist, did you ma	ake changes in your n	nanuscript? *
yes, major changes			
yes, minor changes			
o no			
What were the most import	ant changes you	made as a result of us	sing this checklist?
			<i>\delta</i>
How much time did you spe manuscript *	end on going throu	ugh the checklist INC	LUDING making changes in your
-		with a CONCORT muidal	inna
Not much. The manuscript v	vas prepared as pe	r the CONSORT guidei	ines.
As a result of using this ch	ecklist, do you thir	nk your manuscript h	as improved? *
yes			
○ no			
Other:			
Would you like to become i	nvolved in the CO	NSORT EHEALTH gro	up?
This would involve for examp "Explanation and Elaboration"		ed in participating in a w	vorkshop and writing an
yes			
o no			
Other:			
Any other comments or que	estions on CONSC	RT EHEALTH	

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