Promoting health of Swedish workers by complementary methods - example of a study design of a longitudinal randomized controlled intervention study

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Abstract

Background: When designing, implementing, and evaluating a work site health promotion program, it is necessary to ensure that the program is evidence based. The present article aims to present in-depth information on the design of a longitudinal randomized controlled complementary intervention pilot study that follows the Consort recommendations to evaluate possible effects of a health promotive intervention in healthy workers.

Methods: Employees from four different workplaces were randomly assigned to one of the following groups: i) Massage and mental training (sitting in the armchair and receiving mechanical massage while listening to mental training programs, n=19), ii) Massage (sitting in the armchair and receiving mechanical massage only, n=19), iii) Mental training (sitting in the armchair and listening to mental training programs only, n=19), iv) Pause (sitting in the armchair but not receiving mechanical massage or listening to mental training programs, n=19), v) Control (not sitting in the armchair at all, n=17). The study lasted for eight weeks. Immediately before the randomization, after four weeks and after eight weeks the participants responded to statements from the Swedish Scale of Personality and had their heart rate, blood pressure and fingertip temperature measured.

Results: Receiving mechanical massage and listening to mental training programs, either separately or in combination, during working hours had some positive effects on the employees' own evaluation of their health, as well as their heart rate, blood pressure and fingertip temperature. However, the intervention need to be evaluated further.

Conclusion: The approach described makes it possible to design, implement and evaluate a work site health promotion program, also on pilot-study level and these results should be seen as a first step towards larger randomized studies. This types of studies need to focus on healthy participants and special care should be taken to guarantee adequately powered study groups and their homogeneity.

Key words: Stress, Anxiety, Alternative, Complementary, Intervention, Physical Health, Psychosocial health, Heart rate, Blood pressure, Fingertip temperature, Working place

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1. Background

In high-income countries, stress is a frequent cause of sickness and illness and stress in the workplace is increasing rapidly and has become a challenging factor which affects the health of workers. The number of people who suffer from stress-related illness is increasing, especially within the EU. Reports from the Swedish social insurance agency shows that 26 000 Swedish employees were unable to work due to stress during 2014. This was an increase with 75% from 2012 and it represented 14% of all sick-leaves in Sweden. The numbers continue to increase and by the end of 2016 reactions to stress had become the diagnosis that increased the most among the Swedish working population. Unfortunately, the prognosis indicates that the problem with stress-related illness will continue to increase (1-4).

Stress-related illness typically develops over a long time and most people are detected and diagnosed only after they are already sick, which causes unnecessary suffering and reduced income for the affected person, but also entails large costs for employers and society. The World Health Organization (WHO) has calculated that stress-related illness may decrease a country's gross domestic product (GDP) by as much as 10-20% (5).

Effective health promotive work can help individuals at risk of developing stress-related illness to stay healthy. According to WHO, health promotion is the process of enabling people to increase control over, and improve, their health. Health promotion is not just the responsibility of the health sector but employers also have responsibility for their employees (6).

An increased number of employers have started to work with various methods to help reduce their employees' stress and help them to stay healthy. Two frequently used preventive activities are massage and mental training. They have been shown to induce anti-stress effects such as reduced anxiety and depression, increased perception of wellbeing and decreased perception of pain and, in addition, both heart rate and blood pressure are decreased (7-9). One preventive method, which has been used by several companies in Sweden, is an armchair with massage capabilities and audio programs for mental training. Our research group has with a recent pilot-study, shown that employees who used this armchair during working hours experienced positive psychological effects on self-reported levels of anxiety and stress susceptibility (10). The armchair also had some positive effects on the employees' heart rate, blood pressure and fingertip temperature (11).

To be able to reverse the negative trend about stress-related illness there is a need for well-designed larger evidence-based health promotion studies investigating interventions designed to prevent stress-related illness in workplaces (12). The knowledge gained from these studies would make it possible to develop new and efficient evidence-based therapies to promote health and wellness in workplaces in order to decrease stress and its negative effects on health.

When designing, implementing, and evaluating a work site health promotion program, it is necessary to ensure that the program is evidence based (13). Due to the positive results from our pilot study there is a need to illuminate the methodological approach further. The aim of the present article is therefore to present in-depth information on the design of a longitudinal randomized controlled complementary intervention study that follows the Consort recommendations (14-16) in order evaluate possible effects of a health promotive intervention in healthy workers.

2. Methods

Parts of the methods have been published previously (10, 11). A more detailed description on the design of the longitudinal randomized controlled complementary intervention pilot study, is described as follows.

2.1 Aim of the pilot study

The aim of the pilot study was to evaluate possible effects on employees' experienced psychological health and their physiological health when using mechanical massage and mental training programs, both separately and in combination, during working hours (10, 11).

2.2 The intervention

The intervention used in the study was the Recovery Chair included in the Promas Method™, provided by Promas AB, Sweden. The Recovery Chair is an armchair equipped with mechanical massage programs and the mental training programs. These programs can be used in combination or separately. The mechanical massage has programs for giving massages to the neck, shoulders, back, and calves and the user can adjust the pressure of the massage. The mental training programs are developed and produced by Lars-Eric Uneståhl at Scandinavian International University. The mental training programs include soft music combined with verbal instructions designed to help achieve a relaxing mental state by learning to recover, live in the present, reduce negative stress, think positively, increase the mental strength and to get a greater enjoyment in life. There are also mental training programs for learning to quit smoking and prepare for meetings etc. The Recovery chair had not been scientifically tested and evaluated before this study.

2.3 Participants

2.3.1 Workplaces

Four different work places with no prior experience of the Recovery chair were strategically selected based on their geographical location. The work places were located in small or large towns and the employees working there were living in both urban and rural districts. The included workplaces were both in private and public sectors. The employees who participated in the study worked between 75% and 100% within their own organizations, and they had a variety of positions and responsibilities (Table 1).

The selected workplaces was contacted and informed about the study's purpose and meaning. Upon positive response from the management to let their workplace be included in the study a briefing was held by the research group with the employees at the selected work places. The employees were then given the opportunity to ask questions about the study and their possible participation. All employees who chose to participate in the study signed written consent.

2.3.2 Inclusion criteria

Employees without self-reported serious and/or chronic illnesses (physical or mental) and able to perform their work assignment. The participants should work between 75 % and 100 % within their own organizations.

2.3.3 Exclusion criteria

Employees with previous experience of using mechanical chair massage and/or the mental training programs, as well as employees who were pregnant, or who were, at the time, suffering from influenza, colds, fevers or had a skin or kidney disease were excluded from the study.

For baseline data for all participants see Table 2

2.4 Design

Randomization occurred at each workplace where each participant was randomly assigned to one of the following five study groups: 1) Massage and mental training (sitting in the armchair and receiving mechanical massage while listening to the mental training programs); 2) Massage (sitting in the armchair and receiving mechanical massage only); 3) Mental training (sitting in the armchair and listening to the mental training programs only); 4) Pause (sitting in the armchair but not receiving either the mechanical massage or listening to the mental training programs); and 5) Control (not sitting in the armchair at all). In total, 93 employees participated in the study. (Figure 1).

The study lasted for a total of eight weeks. During these weeks, the participants in groups 1–4 took a break from their regular work and sat in the armchair for 15 minutes three times each week, preferably between 1pm and 4pm. However, in one of the workplaces, due to a hectic schedule, the participants were assigned specific times to use the chair. The Control group (i.e., group 5) continued their work as usual without using the armchair.

The participants who received mechanical massage (i.e., group 1 and 2) all used the same massage program (the recovery program), but were able to make individual adjustments regarding the strength of the massage. The participants who listened to the mental training programs (i.e., group 1 and group 3) listened to different programs in the following order: week 1: ”Recovery”, week 2: “Mindfulness–learn to live in the present”, week 3: ”The way to a better and deeper sleep”, week 4: “Reduce the negative stress”, week 5: "Learn to think positively”, week 6: "Increase your mental strength”, week 7: “How to get a greater enjoyment of life and week 8: ”Recovery”. The participants in the Pause group (i.e., group 4) took a break from their regular work and sat in the chair, however they did not use either the massage program or listen to the mental training programs.

At the workplaces, all the armchairs were located in rooms where the doors could be shut, so that that user could be completely separated from other activities while sitting in the chair.

2.5 Data collection

The data collection took place at the work places during regular working hours. Data was collected during individual meetings with each participant on three different occasions during the study period. The first occasion was at the start of the study, immediately before the randomization, so that the participants were not influenced by knowing which group they would belong to. The second time was after four weeks (half way through the study) and the third time was after eight weeks (end of study). During all three occasions data was collected to evaluate the employees’ experienced psychological health and their physiological health. All data was collected by researchers who were well trained and with previous experience in this kind of data collection.

2.5.1 Primary outcome

The primary outcome was the effect on employees’ experienced psychological health.

The participants answered a web-based questionnaire (Eva Sys, Alcom System AB, Stockholm, Sweden) regarding their self-experienced physical, mental and social health. The statements included in the questionnaire were part of the larger questionnaire “the Swedish Scale of Personality” (SSP) which is a revised form of the previous “Karolinska Scale of

Personality" (KSP). In SSP the scales have been shortened, modernized and psychometrically evaluated. The SSP has been evaluated for more than 3000 individuals including more than 1000 patients. SSP contains 13 subscales where each subscale has seven statements with a four point response format, ranging from "does not apply at all" to "apply completely" (17). In the present study the following five subscales, and corresponding items, were included: "Somatic Trait Anxiety" (includes somatic related anxiety such as sweating, teeth clenching or not getting enough air to breathe), "Psychic Trait Anxiety" (includes psychic related anxiety such as an expression of not having much self-confidence, to be worried about things or to be a person who is excessively sensitive and easily hurt), "Stress Susceptibility" (includes aspects of having less energy or feeling more hurried and stressed than most other people, feeling pressure when told to speed up work or having less energy than most other people), "Detachment" (contains social dimensions such as keeping people at a certain distance or being reserved and cold rather than warm and kind) and "Social Desirability" (contains claims such as always being polite and self-controlled, always being a good listener or being willing to admit a mistake).

When answering the questionnaire the participants were alone in a secluded room.

2.5.2 Secondary outcome

The secondary outcome was the effect on employees' physiological health, which included effects on their heart rate, blood pressure and fingertip temperature.

The participants' heart rate and systolic and diastolic blood pressure were measured using an automatic manometer that was clinically validated and approved in accordance with the protocols of the International Society of Hypertension. (Omron M6 Comfort, Omron Healthcare, Hoofddorp, the Netherlands). The manometer was attached on the participants' left arm and placed in line with the heart. Fingertip temperature was measured with a laser thermometer (Digital-Laser Thermometer, Esska.de GmbH, Hamburg, Germany). The participants were in a seated position during all measurements.

2.6 Statistical analysis

Statistical calculations were performed using the IBM Statistical Package for the Social Sciences (SPSS, version 22.0). Since the number of participants in each group was relatively small and a normal distribution could not be taken for granted, non-parametric statistical tests were used to analyse the results. To test for differences between groups on the separate occasions (start, four weeks, and eight weeks) the Kruskal Wallis Test for independent samples, as well as the Mann-Whitney Test for independent samples were used. To test for differences within each study group during the entire study period Friedman's Two-way Analysis of Variance by Rank was used. To test for differences between two occasions within each study group the Wilcoxon Signed-Rank Test was used. Changes were analyzed between start and four weeks, between four and eight weeks, and between start and eight weeks. Since this was an exploratory pilot study we chose to perform the paired test independently of the results from the Friedman test. p-values$\leq$0.05 were considered significant and p-values<0.1 were interpreted as tendencies.

2.7 Ethical considerations

The study was approved by the Local Ethics Committee in Gothenburg, Sweden (980-12) and the Helsinki Declaration was followed. All participants were informed about the aim of the study, the course of action, that they could end the study at any time without

giving any reason and that their workload would not be affected by their participation. All collected data were treated confidentially and was only available to the researchers, not to their employers.

The risks associated with this type of study was considered minimal. The use of the intervention is not known to cause any physical or mental pain or discomfort to persons and according to former users of the intervention, there are no known side effects.

The control group were not allowed to use the armchair during the study period but they had the opportunity to use the same armchair for eight weeks after the study had ended. All employees who chose to participate in the study signed written consent. The study was registered in Australian New Zealand Clinical Trials Registry (ACTRN12615000020583, Date of registration: 15/01/2015).

2.8 A multidisciplinary research group

To accomplish a multidisciplinary study as presented above it requires that expertise from many different fields related to health are working together. Our research group joins scientists from biomedicine, public health and nursing, but also includes expert knowledge from the companies Promas AB (working with recovery in the workplace) and Scandinavian International University (working with mental training).

3. Short summary of the results

3.1 Primary outcome

There were no significant differences between the five study groups for any of the traits studied ("Somatic Trait Anxiety", "Psychic Trait Anxiety", "Stress Susceptibility", "Detachment" and "Social Desirability") at any of the occasions. However, the massage group showed a significant decrease in the subscale "Somatic Trait Anxiety" (p=0.032), during the entire study period. Significant decreases in the same subscale were also observed in the pause group between start and week eight (p=0.040) as well as between week four and week eight (p=0.049) and also in the control group between the second and third data collection (p=0.014). The massage and mental training group showed a significant decrease in "Stress Susceptibility" between week four and week eight (p=0.022). The pause group showed a significant increase in the subscale "Detachment" (p=0.044) (10).

3.2 Secondary outcome

Between-group analysis showed that heart rate differed significantly between the groups after 4 weeks (p=0.020) and tended to differ after eight weeks (p=0.072), with lowest levels displayed in the massage group and the control group. Blood pressure and fingertip temperature did not differ between the groups. Within-group analysis showed that mechanical massage decreased heart rate (p=0.038) and blood pressure (systolic p=0.019, diastolic p=0.026) and increased fingertip temperature (p=0.035). Mental training programs reduced heart rate (p=0.036). Combining the two methods increased diastolic blood pressure (p=0.028) and decreased fingertip temperature (p=0.031). The control group had a significant decrease in systolic blood pressure during the first four weeks of the study (p=0.038) (11).

4. Discussion

This article describes a methodological approach, to present in-depth information on the design of a longitudinal randomized controlled complementary intervention study, in order evaluate possible effects of a health promotive intervention in healthy workers. When designing, implementing, and evaluating a work site health promotion

program, it is necessary to ensure that the program is evidence based (13). In order to gain acceptability and face validity for the items and statements used in a study, a pilot study should always be performed (18). The study we present was a pilot study with some limitations (discussed further below) but it still shows to the strengths of randomized controlled intervention studies and future studies should always strive to have a randomized controlled study design, even for pilot studies. There are some lessons learned from the pilot study that are of importance to highlight and that will be discussed below.

When studying health promotive interventions for workers it's important to keep in mind that aim is to help healthy workers stay healthy, not to treat workers who have become ill and unable to work (19). Therefore the studies need to focus on healthy participants. However, it is still important to have understanding for that even healthy workers are probably affected by stress, but not in such a severe way that they have become ill. In our pilot study we defined healthy workers as workers able to perform their work assignment and who had not reported any serious or chronic illnesses (physical or mental). This doesn't mean that they were not affected by stress. When looking at the workers who declined participation the main reason they stated was "An already too stressful working situation". Therefore we assumed that the participants who decided to participate also experienced a stressful working environment.

The tools for evaluating interventions such as the one used in our study should be selected based on the health promotive perspective but still be suitable for the purpose of the study and able to detect changes for the healthy participants.

Since the purpose of our exploratory pilot study was to include a variety of workplaces and duties the study included four different types of workplaces, with the participants being both men and women from socioeconomically different groups (For baseline data see Table 2). However, when looking in hindsight this might have complicated the interpretation of the results. For future studies we recommend to focus on more homogenous groups to get more clear results.

When discussing study groups it is impossible not to address the question of sample size. In our pilot study 93 participants were randomly assigned to one of five different study groups (including a control group). In future studies it would be interesting to measure also the participants' salivary cortisol levels and if it should be possible to detect a 30% reduction of the individual's cortisol levels in the intervention groups compared with the controls (b=0.8 and a=0.05) each group should include 100 individuals. With that many participants it would also be possible to consider different background variables in the statistical analysis, e.g., gender, type of positions in the companies, leisure activities etc. Due to financial as well as timely limitations for the present pilot study it was not possible to perform an adequately powered study. Therefore, the results from this pilot study should be seen as a first step towards larger randomized studies within this area.

4.1 Conclusion

Through a randomized controlled study design that follows the consort recommendations it can be possible to design, implement and evaluate a work site health promotion program. This approach should also apply for pilot studies whose results should be seen as a first step towards larger randomized studies within the area. When designing this types of studies focus should be on keeping healthy workers stay healthy and therefore the studies need to focus on healthy participants. Special care should also be taken to guarantee adequately

powered study groups and their homogeneity.

5. Funding

This study was funded by the The Knowledge Foundation, Sweden, www.kks.se, (reference number: 20110142). The study was a co-production project including: University of Skövde,

Promas AB (provided the armchair with mechanical massage) and Scandinavian International University (provided the mental relaxation program).

6. Conflict on interests

No conflict of interest, including institutional, personal, financial, and other influences are to be reported.

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7. References

1. Authority SWE. Work-Related Disorders. 2016.
2. EU-OSHA. European Agency for Safety and Health at Work 2017 [Available from: https://osha.europa.eu/sv.
3. Förskringskassan. Stress vanligaste orsaken till sjukskrivning 2015 [Available from: https://www.forsakringskassan.se/!ut/p/z0/LYyxDsIwDAW_hSFzgtjYKsQXsFRdIotYJcR9iWI3_D5FYjrdDecXP_sFNPJKlitIDp8_z-3ayF7ufJlcuFUYwx53F1pn1T82TomFkBguqP1SHAQ5Tmoca1cqjGhZJOp7L1p6HshYfSvT6QubSPgF/.
4. Försäkringskassan. Sjukskrivningar på grund av anpassningsstörningar och reaktioner på svår stress ökar mest 2016 [Available from: https://www.forsakringskassan.se/!ut/p/z0/LYgxDoAgDADf4sCMxs3NGF_gYlhII40iUgit-n0ZXO5yp41etSF4_A7iE8FVe323OGSQQ3X9qNopkSDJMqs2F2T-FdE5vIAcUj3R8nkHDsU_5GmHYlOoiMiicxibDz4tbKM!/.
5. WHO. Global Health Risks - Mortality and burden of disease attributable to selected major risks. 2009.
6. World Health Organization W. Workplace health promotion www.who.int2014 [Available from: http://www.who.int/occupational_health/topics/workplace/en/index1.html.
7. Field T. Massage therapy research review. Complementary therapies in clinical practice. 2014;20(4):224-9.
8. Uneståhl L-E, Bundzen P, Gavrilova E, Isakov V. The effects of integrated mental training on stress and psychosomatic health. Hypnos. 2004;XXXI(2):83-5.
9. Uvnäs-Moberg K, Handlin L, Petersson M. Self-soothing behaviors with particular reference to oxytocin release induced by non-noxious sensory stimulation. Frontiers in psychology. 2015;5:1-16.
10. Muller J, Handlin L, Harlen M, Lindmark U, Ekstrom A. Mechanical massage and mental training programmes affect employees' anxiety, stress susceptibility and detachment-a randomised explorative pilot study. BMC Complement Altern Med. 2015;15:302.
11. Muller J, Ekström A, Harlén M, Lindmark U, Handlin L. Mechanical massage and mental training programs effect employees' heart rate, blood pressure and fingertip temperature—An exploratory pilot study. European Journal of Integrative Medicine. 2016;8(5):762-8.
12. Ruotsalainen J, Serra C, Marine A, Verbeek J. Systematic review of interventions for reducing occupational stress in health care workers. Scand J Work Environ Health. 2008;34(3):169-78.
13. Linnan L, Peabody KL, Wieland J. Health Promotion Programs In Workplace Setting. In: Fertman CI, Allensworth DD, editors. Health Promotion Programs: From Theory to Practice: Wiley; San Francisco, CA: Jossey-Bass; 2016; 2nd ed .
14. Altman DG, Schulz KF, Moher D, Egger M, Davidoff F, Elbourne D, et al. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. Ann Intern Med. 2001;134(8):663-94.
15. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P, Group C. Methods and processes of the CONSORT Group: example of an extension for trials

assessing nonpharmacologic treatments. Ann Intern Med. 2008;148(4):W60-6.

16. Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, Haynes B, et al. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. BMJ. 2008;337:a2390.
17. Gustavsson JP, Bergman H, Edman G, Ekselius L, von Knorring L, Linder J. Swedish universities Scales of Personality (SSP): construction, internal consistency and normative data. Acta Psychiatr Scand. 2000;102:217–25.
18. Machin D, Campbell M, J,. The Design of Studies for Medical Research. Chichester, England, Great Britain.: John Wiley & Sons, Inc.; 2005.
19. Eriksson, M., Lindström, B. A salutogentic interpretation of the Ottawa Charter – Debate. In: Health promotion international, 2008):Vol. 23;No 2.

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8. Tables

Table 1: Overview of the four workplaces, type of positions, responsibilities and the participation of women and men.

Workplace	Type of workplace	Type of positions and responsibilities	Women	Men	Total
School sector	School, Preschool	Teacher, preschool teacher, cleaner, principals	24 80%	6 20%	30 100%
Health-care sector	Primary health-care center	Registered nurses, auxiliary nurses, physicians, chiropodists, head nurses	18 94.7%	1 5.3%	19 100%
Automotive industry	Manufacturer of heavy trucks	Councils, economists, clerks, head clerks, administrative staff, engineers	12 75%	4 25%	16 100%
Construction industry	Manufacturer of energy-efficient insulation solutions	Manager, administrative staff, sellers, engineers	15 53.6%	13 46.4%	28 100%
			Total: n=69 74.2%	Total: n=24 25.8%	Total: n=93 100%

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Table 2: Baseline data for the randomized groups (n=93)

Groups	**Massage and mental training (n=19)**	**Massage (n=19)**	**Mental training (n=19)**	**Pause (n=19)**	**Control (n=17)**
Age					
Mean	50.4	46.5	49.3	47.9	46.6
(SD)	(8.37)	(12.1)	(14.1)	(9.24)	(10.5)
Sex					
Woman. n (%)	16 (84.2)	15 (78.9)	13 (68.4)	13 (68.4)	12 (70.6)
Men. n (%)	3 (15.8)	4 (21.1)	6 (31.6)	6 (31.6)	5 (29.4)
Marital status					
Single. n (%)	3 (15.8)	3 (15.8)	2 (10.5)	2 (10.5)	2 (11.8)
Partner/married. n (%)	15 (83.3)	16 (84.2)	17 (89.5)	17 (89.5)	14 (82.4)
Living apart/other. n (%)	0	0	0	0	1 (5.9)
Education					
Compulsory school. n (%)	1 (5.3)	1 (5.3)	1 (5.3)	0	1 (5.9)
Senior high school. n (%)	5 (26.3)	3 (15.8)	2 (10.5)	4 (21.1)	2 (11.8)
Higher education. n (%)	2 (10.5)	3 (15.8)	2 (10.5)	3 (15.8)	1 (5.9)
University. n (%)	11 (57.9)	12 (63.2)	14 (73.7)	12 (63.2)	13 (76.5)

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9. Figure

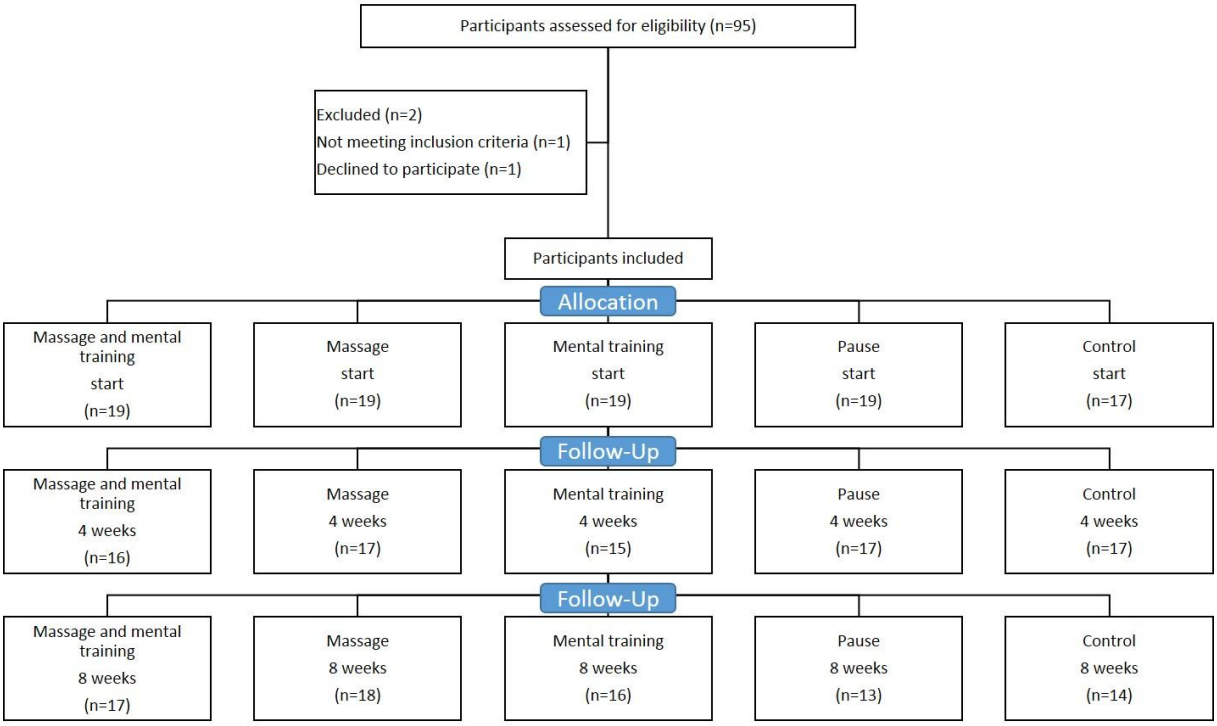

Figure 1: Flowchart of the 93 employees' participants enrolled in the pilot study, randomly assigned to one of the five study groups.