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# Perspectives of elderly trial participants with hypertension on modes of delivery of individual summary reports: Study within a trial protocol

Short title: Delivery of individual summary reports

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## Abstract

**Background:** Sharing results with individuals and the lay public following participation in a trial is an ethical imperative. In a research scenario where transparency is a widely accepted priority, providing individual results should be the norm. However, there are scarce recommended practices regarding the items to be included in the data communication and how to disseminate it. This Study Within a Trial (SWAT) is hosted by the multicenter, randomized study “Hypertension Approaches in the Elderly: a Lifestyle study” by using public and patient involvement. We aim to explore two different face-to-face formats (individual or group contexts) for delivering individual results to older participants (age  $\geq 60$  years old), assessing the understanding, satisfaction, and short-term psychological well-being generated by different delivery formats.

**Methods:** This SWAT is a randomized, single-blinded for outcomes assessors, parallel group intervention. The design consists of four distinct stages: (1) invitation and inclusion of participants (2) randomization of participants to either an individual or a group-based face-to-face dissemination format; (3) delivery of individual results in the two different formats; and (4) self-administered questionnaire to determine aspects of understanding (primary outcome), satisfaction and short-term psychological impact generated by the individual results delivery format.

**Discussion:** Researcher-participant communication by feeding back study results is a way to acknowledge the vital role that each participant plays in the scientific process and add value to their participation. This protocol provides a template for other trialists who wish to enhance scientific communication in disseminating individual results that contemplate the elderly population's profile.

Registration:

Northern Ireland Hub for Trials Methodology Research SWAT Repository (SWAT122).

HAEL trial NCT 03264443.

Keywords: Dissemination, Health communication, Older, Public and patient involvement, Study within a trial

## **Background**

Transparency in clinical research is essential for the consolidation of the evidence-based approach (1,2). The implementation of transparent practices may foster the credibility and robustness of research, contributing to a reproducible, reliable, and accessible science (3). A broad movement of transparent practices in clinical trials has promoted study registration, the deposit of publicly available protocols, and reporting guidelines (e.g., SPIRIT and CONSORT) to increase the quality of reporting from the planning to the scientific dissemination stages (4,5). However, for comprehensive research transparency, it is relevant to encourage patients and the public to be more actively involved in different stages of a research project (6).

The results of clinical trials are mostly presented as abstracts at research conferences and published in scientific journals. Research projects rarely include any formal provision to provide feedback directly to the study participants (7). However, disseminating research results to participants is a way to acknowledge their critical roles in the studies and increase the value of their participation (8). Sharing research results is considered good practice in research and a principle which the World Health Organization (WHO) sees as essential (9), indicating that the main results should be made available to the public after the study is completed. In addition, researchers mention that participants must have the option of receiving results, either involving individual results of the evaluations carried during the study (10,11) or a summary of aggregated study results (8).

Disseminating research results to non-academic audiences may empower and engage study participants, as well as provide knowledge for clinicians (whenever applicable) and policymakers (12). Upon receiving the results, the participants feel recognized for their contribution to the trial (13), with evidence that learning about the results has a significant impact on their lives (14). Among participants' reasons for wanting study results, the clinical interest stands out (for prevention, treatment, and understanding of the disease), the respect for their participation, the right to know their data, and the possibility of increasing public awareness of the importance of research (15).

The participants' desire to receive aggregated study results or individual reports derived from tests carried out during the research has been investigated in different areas (8,15–18). Although some institutional documents exist to promote this practice (2,10,19), a survey with trial authors indicated that the minority of respondents reported (27%) or planned to report (13%) the clinical trial findings to participants (20). These data may derive from unawareness of the importance of disseminating results to participants and linked

communities. In addition, such practices still receive few incentives from institutional bodies (20) and may reflect the scarcity of guidelines and standardized procedures of which items should be included in data communication (19).

The dissemination of research results has been mostly addressed in the areas of cancer or genetics (15,21,22). A review consisting of 28 studies that included the communication of research results indicated that 43% (12 studies) involved cancer research and 25% (7 studies) involved genetics research (15). The findings of a study in cardiac rehabilitation suggest that men over 65 years of age prefer to be informed of the study's aggregated results in meetings (16), while elderly participants in other studies mentioned preference and satisfaction in receiving individual results in a letter format (13,23). Few studies report about the approach of sharing clinical trial results (e.g., report of clinical examination, blood chemistry results, mobility testing) in elderly populations (13,23). Thus, uncertainty persists regarding the type of information and the formatting to be used while considering participants' perspectives (13).

The present Study within a trial (SWAT) is hosted by the multicenter, randomized study "Hypertension Approaches in the Elderly: a Lifestyle study" (HAEL Study). In this study, we aim to explore two different face-to-face formats (based on individual or group contexts) for delivering individual results to older participants (age  $\geq 60$  years old), determining the effects on understanding, satisfaction, and short-term psychological well-being. The study has an exploratory characteristic, with no directional hypothesis regarding which of the assessed format for the dissemination of individual results that could be more appropriate to the elderly population.

## **Methods**

This SWAT is registered on the Northern Ireland Hub for Trials Methodology Research SWAT Repository (SWAT122).

### **Study Design**

This SWAT is a randomized, single-blinded for outcome assessors, parallel group intervention hosted by "Hypertension Approaches in the Elderly: a Lifestyle study" multicenter, two-arm, randomized trial (HAEL Study) (NCT03264443) (24). The Hael Study is a confirmatory trial comparing the efficacy for blood pressure control by a pragmatic combined training program versus a health education program in older adults with hypertension.

## **Setting**

The methodological phases will be conducted at the Clinical Research Center of the Hospital de Clínicas de Porto Alegre, Porto Alegre, RS, Brazil.

## **Population and sample size**

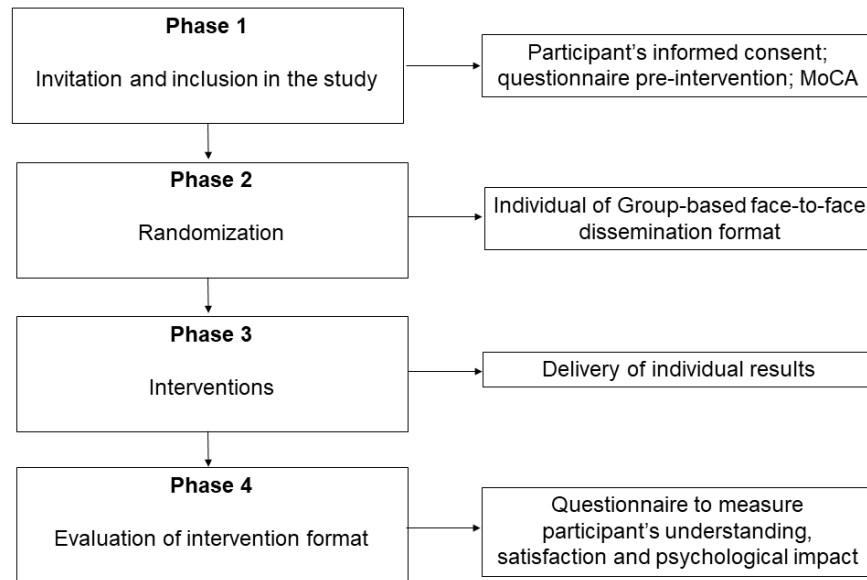
As this is a SWAT within the HAEL Study, recruitment, screening, and eligibility criteria will follow the main study approved by the Institutional Review Board of our institutions (CAAE: 62427616.0.1001.5327 and CASE: 62427616.0.2001.5313) with published protocol available:

<https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-019-6970-3>.

Eligible participants will be those who were randomized in the HAEL Study and started the interventions in or after July 2019. To be eligible, participants also need to have achieved a minimum attendance of 25% in the intervention sessions, which translated into 3 sessions in the health education program or 9 sessions in the combined training program. Thus, the sample size is expected to have approximately one quarter of the participants in the HAEL Study, with a total target of 50 participants to be included from the coordinator centre (Porto Alegre).

## **The SWAT**

The design consists of four distinct phases (see Figure 1). Phases 1 and 3 will be conducted by the same investigator (certified physiotherapist).



### **Phase 1. Invitation and inclusion in the study**

After completing one of the two HAEL Study interventions, all participants will be invited to participate in the SWAT. For that, the research team will contact each one by phone, and, if the patient shows interest, schedule an in-person meeting to clarify the study procedures. During the meeting, a trained investigator will handle the volunteer's informed consent, providing necessary clarifications about the study objectives, procedures, random allocation, experimental and survey procedures, and the potential risks and benefits involved in the study protocol. Once a subject decides to participate, they will be invited to complete a questionnaire including sociodemographic characteristics and questions about expectations when receiving their study results.

After this, the Montreal Cognitive Assessment (MoCA) test, a rapid screening instrument for mild cognitive dysfunction, will be carried out by a certified researcher with proper training (<https://www.mocatest.org/>). A total time of 90 minutes is estimated for this visit.

### **Phase 2. Randomization and allocation concealment**

The generation of allocation sequence will be based on computer-generated random numbers (random.org), with a 1:1 ratio, stratified by group on the main trial and with permuted blocks of random sizes that are not disclosed to ensure concealment.

Allocation concealment will be implemented by an independent researcher (D.U) not involved with the intervention and data collection. The investigator in charge of requesting the code to allocate subjects, will fill an online request whenever one or more subjects have completed the previous stages and may enter an intervention arm. Thus, the aforementioned researcher (D.U) will consult the code in consecutive order and uncover the code relative to the requested subject(s).

Due to the nature of the interventions, neither the researcher who will deliver individual results nor the participants will be blinded. Blinding will be implemented for outcome assessors and data analysts of primary and secondary outcomes listed in this protocol.

### **Phase 3. Interventions**

The delivery of the printed document with the individual results of the participants will be carried out face-to-face (individually or in a group) at the Clinical Research Center of the Hospital de Clínicas de Porto Alegre. Participants will be welcomed in a meeting room for delivery, explanation and clarifications of the individual summary reports. More details of interventions:

Intervention 1: Individual face-to-face dissemination format (the researcher with one participant). The researcher will deliver the report and will read the results together with the participant, explain the data and clarify any doubts that arise. The visit should last 15 minutes.

Intervention 2: Group-based face-to-face dissemination format (one researcher with 4 to 6 participants). The delivery of the report document with individual results will be made available to each participant at the beginning of the activity, so that they can follow their own information during the meeting. The standardized explanation from the researcher should last less than 15 minutes, guided by a slide presentation. Afterward, participants will be allowed time for questions, which should last 15 minutes. Due to possible interaction and contribution between participants, the total duration should last up to 30 minutes.

If any of the participants drawn for the group disclosure format ask for further clarification after the delivery of their results, a second visit will be scheduled for individual clarification.

The information in both delivery formats will be standardized, including the project title, an initial message with the purpose of the study, acknowledgment to his/her participation, and guidance on the disposition of results presented in the report. The individual results are based on testing outcomes derived from assessments conducted before (baseline) and after the HAEL interventions such as: blood chemistry, body composition, functional and strength performance, office blood pressure (together with reference values available in the literature), cardiopulmonary exercise test, and ambulatory blood pressure monitoring (Appendix 1).

#### **Phase 4. Evaluation of intervention format**

After delivery of individual results, participants will have a 15-minute break before completing the self-administered questionnaire to determine aspects of understanding, satisfaction, and short-term psychological impact generated by the individual results delivery format.

The non-validated questionnaire includes 21 items (Appendix 2) that were adapted from existing questionnaires (13,14,23,25–27) and consultation with health professionals involved in the HAEL Study.

Instructions for completing the questionnaire will be conducted by a trained research staff graduating in Physiotherapy. The questionnaire includes questions on a 5-point Likert scale and multiple choice single answer questions. It is estimated to take a maximum time of 30 minutes to complete it.

#### **Outcomes**

The outcomes are related to measures of understanding, satisfaction, and short-term psychological impact generated by the modes of handing results to participants.

##### ***Primary***

Understanding of individual results by participants, assessed through a non-validated questionnaire with five questions of multiple choice.

##### ***Secondary***

Satisfaction with the dissemination format, clarity of information assessed through Likert scale questions, and psychological impact upon receiving individual results, assessed in Likert scale questions.



### **Measure of primary outcome**

The items of questionnaire considered for evaluation of the understanding domain will regard the results of: (i) low-density lipoprotein (LDL) cholesterol; (ii) body mass index; (iii) functional test battery; (iv) office blood pressure; (v) cardiorespiratory capacity (items 16,17,18, 20, 21, Appendix 2). For each question, there is only one correct answer, which will be variable, according to the individual participant data. Thus, the researcher will prepare a response template and analyze the score of correct answers for each participant. The score ranges between 0 and 5 points, being "0" the most adequate interpretation of results and "5" an incorrect interpretation of a given individual result.

### **Measure of secondary outcome**

The satisfaction will be assessed through the domains: object, quality, and effect of delivery include question 2-9 of the questionnaire, measured by a Likert scale of 5 points. A score of 5 refers to when the participants are very satisfied with the questioned domains.

The psychological impact will be assessed through the following emotional manifestations (questions 12 to 15, Appendix 2) after knowing the results: (i) level of concern; (ii) level of anxiety; (iii) fearful feelings; and (iv) sad feelings. For the scores' analyses, the results will be recorded for equivalence with the other data on the Likert scale, so score 5 is worth 1, score 4 is worth 2 and thus with the other scores.

Questions that are not addressed for the analysis of outcomes (10,11 and 19) will be analyzed and discussed separately.

### **Measure MoCA Test**

The MoCA screening instrument, for evaluating cognitive function, considers different domains: attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation (28). The time needed to administer the MoCA test is approximately 10-15 minutes.

The MOCA will be used to control the possible influence of a confounding variable (cognitive function) on the assessment of the main outcome. The test has a total score possible of 30 points; a score of 26 or above is considered normal. The researcher will sum all subscores listed on the document, according to standardized guidelines for the use of

the instrument, and will add one point for the individuals who have 12 years or fewer of formal education (28).

### **Statistical considerations**

Answers from participants will be analysed using descriptive and inferential statistics. Ordinal logistic regression will be used to evaluate the difference between groups in some variables of the Likert scale, defined a priori. The  $\alpha$  adopted for the inferences will be 0.05.

For the evaluation of a single answer questionnaire, the sum of items will be used to generate a score of correct answers (range 0 to 5). Such data distribution will be assessed by the Kolmogorov-Smirnov normality test. Normally distributed data will be presented as means and standard deviation, whereas medians and interquartile range will be used if the data show a skewed distribution. The group summed scores will be compared by either one-way analysis of variance (normal distribution) or Mann-Whitney test (non-parametric alternative).

### **Harms**

There are no known physical harms from participating in the research. However, some psychological discomfort can be caused if alterations appear in any of the tests performed. If the participant presents any test result that warrants further medical care and/or investigation the participant will be warned and advised to seek medical advice.

### **Dissemination**

We aim to disseminate the findings of the SWAT to as many stakeholders as possible - participants, academic and non-academic community, researchers, research funders. Our dissemination plan will include meeting with study participants by which we will present a layman-friendly explanation about the study design, findings, and interpretation, and also via peer-reviewed publications and conference presentations. Anonymised data will be made available on an open access repository (<https://osf.io/d4mfs/>).

### **Discussion**

Transparency in research represents an important aspect in the scientific world and stands out as a growing and widely accepted priority among stakeholders (3,7,29). Initiatives such as the involvement of the patient and the public in the different stages of a research contribute to a more transparent process (30), improving the completeness of the reporting of clinical trials (4,5,31). Thus, in respect and appreciation for the central role of the participant in conducting the research, it is their right to receive individual data, as well as the results of the trial through an appropriate process of dissemination and effective communication.

Whenever planned, the communication of individual results should be carried out taking into account the perspectives, preferences and needs of research participants (15,31). Since the participant-researcher communication may influence personal decision-making and cause emotional impacts such as anxiety, sadness and worry (8,10,15, 18), we underscore the importance to describe how older adults understand and respond to the delivery of their data generated through participation in a clinical trial. In this regard, the SWAT - HAEL study stands out for evaluating and exploring ways to conduct a communication process to deliver health reports for elderly participants, through the evaluation of two formats which may, at some extent, influence understanding, satisfaction and short-term psychological impact.

Although this SWAT will present a sample size limited in respect to the remaining participants in the host trial, we expect to foster patient and public involvement in research, as well as provide evidence to inform future more comprehensive guides on the communication of individual results for the elderly population.

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