SWAT 122: Perspectives of elderly trial participants with hypertension on modes of delivery of individual summary reports

Objective of this SWAT
Our overarching goal is to gain knowledge on different formats to deliver summaries of results to older participants in a clinical trial. We will compare the effects of two distinct face-to-face formats (based on either individual or group settings) on outcome comprehension, satisfaction, psychological issues and cognitive function.

Study area: Outcomes
Sample type: Participants
Estimated funding level needed: Low

Background
In order to support greater transparency and accountability with research participants, the dissemination of clinical trial data is considered to be a best practice process by the World Health Organization [1,2]. However, dissemination of clinical trial results is generally done through scientific publications or other types of exchanges within the community of researchers, academics or healthcare providers [3]. Beyond technical materials, studies about dissemination to lay people and trial participants are limited. There are few standardized practices or guidelines on the items to include in reporting and how this information should be provided [4,5], especially for trials involving the elderly [6].

This SWAT will help to fill this gap by evaluating different formats for returning individual information to research participants, determining the effects on understanding, satisfaction and short-term psychological wellbeing. This SWAT is hosted in the "Hypertension Approaches in the Elderly: a Lifestyle study" multicentre, randomized trial (HAEL Study) (NCT03264443) [7].

The sample will be based on approximately one quarter of the participants in the HAEL Study, which will be a total of 50 participants to be included from the coordinator centre (Porto Alegre). Participants will be randomized to a face-to-face, individual dissemination format or a face-to-face, group-based individual dissemination format (with 4 to 6 participants per group). In both formats, there will be standardized document delivery with test and exam information. Participants will be asked to complete a self-administered questionnaire to determine aspects of understanding, satisfaction and short-term psychological impact.

Interventions and comparators
Intervention 1: Individual face-to-face dissemination format (one researcher with one participant). Participants will be individually welcomed by a trained researcher in a private room for delivery, explanation and clarification of the individual results. The visit should last less than 15 minutes.
Intervention 2: Group-based face-to-face dissemination format (one researcher with 4 to 6 participants). Participants be welcomed in a meeting room by a trained researcher for delivery, explanation and clarifications of the individual summary reports. 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 slide presentation. Afterwards, participants will be allowed time for questions, which should last less than 15 minutes. Due to possible interaction and contribution between participants, the total duration should last up to 30 minutes.

Index Type: Method of Dissemination, Participant Information

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Understanding of individual results by participants, assessed through a non-validated questionnaire with multiple choice single answer questions.

Secondary: Satisfaction with the proposed dissemination format, clarity of information and possible psychological impact upon receiving individual results, assessed through a non-validated Likert scale questionnaire.

Analysis plans
Participant responses 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.
For the evaluation of a single answer questionnaire, the sum of items will be performed to compose a score and the distribution of data will be assessed by the Kolmogorov-Smirnov normality test. Normally distributed data will be presented as means and standard deviation and these will be used to compare data with normal distribution, Student's t test and two-way analysis of variance (ANOVA) with repeated measures will be used. If the data have an asymmetric distribution, medians with an interquartile range will be used and data analysis with asymmetric distribution will be conducted using the Mann-Whitney test. The α adopted for the inferences will be 0.05.

Possible problems in implementing this SWAT
(1) Participants may want to receive results through our standard approach (individual, face-to-face), and therefore not consent to participate in this SWAT. If this happens, it would reduce our recruitment capacity and we might not reach the projected sample size.
(2) If any delivery format results in incorrect or insufficient understanding among the participants, we will need to offer a follow-up visit or telephone call for clarification. If this occurs, the follow-up procedures will take place after the participant has completed their outcome assessment for this SWAT.

References
1. Moorthy VS, Karam G, Vannice KS, Kieny M-P. Rationale for WHO's New Position Calling for Prompt Reporting and Public Disclosure of Interventional Clinical Trial Results. PLOS Medicine 2015; 12(4):e1001819.
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3. Chen PG, Diaz N, Lucas G, Rosenthal MS. Dissemination of Results in Community-Based Participatory Research. Am J Prev Med. 2010; 39(4):372-8.
4. Fernandez CV, Kodish E, Weijer C. Informing Study Participants of Research Results: An Ethical Imperative. IRB. 2003; 25(3):12-9.
5. National Academies of Sciences, Engineering, and Medicine. 2018. Returning Individual Research Results to Participants: Guidance for a New Research Paradigm. Washington, DC: The National Academies Press. https://doi.org/10.17226/25094.
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7. Umpierre D, Santos LP, Botton CE. et al. The "Hypertension Approaches in the Elderly: a Lifestyle study" multicenter, randomized trial (HAEL Study): rationale and methodological protocol. BMC Public Health 2019; 19(657):1-13.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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