

SWAT 208: Comparative Effectiveness of a Self-Directed Online versus a Phone Call Enrolment Process

Objective of this SWAT

To evaluate the comparative effectiveness of a self-directed online enrolment process in comparison to a phone call enrolment process in a randomised trial

Study area: Recruitment, Enrolment

Sample type: Participants

Estimated funding level needed: Very Low

Background

The evidence for the scale-up and sustainability of community health interventions is limited, including for sport-setting based interventions.[1] This includes limited knowledge of the most effective and efficient post-trial ('real world') enrolment processes. There is also limited evidence of how digital web-based tools can be used most effectively to help enrol participants in randomised trials. For example, the Prioritising Recruitment in Randomised Trials study identified that answering the question "what are the advantages and disadvantages to using technology during the recruitment process?" is one of the top ten research priorities for trial recruitment and concluded that there was "no evidence available" to answer this question.[2]

Adapted from the successful UK-based Football Fans in Training program, Aussie Fans in Training (Aussie-FIT) is an evidence-based sport-themed men's health behaviour change intervention that is highly attractive to men.[3] Pilot work has demonstrated promising physical and mental health outcomes.[4] In that Aussie-FIT pilot work, participants completed a brief web-based expression of interest form. Prospective participants were then contacted by a researcher and scheduled an enrolment appointment via a 10-15 minute screening phone call.[5] Community sporting club representatives in Australia have highlighted to the Aussie-FIT team that the administration burden involved in receiving phone calls to enrol participants would present a significant barrier to running Aussie-FIT outside of trial conditions. For the program to be scaled-up and sustainable outside of research conditions, a more efficient enrolment process is required.

In response to this stakeholder identified barrier, we co-designed a self-directed online enrolment process with consumers and stakeholders. The Aussie-FIT multi-State/Territory hybrid effectiveness-implementation RCT (ACTRN12623000437662) provides an opportunity to embed a study within a trial (SWAT) to evaluate the comparative effectiveness of the self-directed online and phone call enrolment processes. Trial recruitment and marketing materials direct prospective participants to complete a brief online expression of interest (EOI) and eligibility screening survey (Qualtrics) via the Aussie-FIT website. If prospective participants meet the study eligibility criteria, they are automatically randomised to one of two enrolment conditions.

Interventions and comparators

Intervention 1: Phone Call Enrolment: on completion of the online EOI, eligible prospective participants receive an on-screen message indicating that they will be contacted by phone to complete their enrolment. Within 7 working days, researchers will call participants using a standardised enrolment phone script that provides information about the Aussie-FIT program and study. Researchers will schedule the baseline appointment during this phone call. On completion of this process all details will be confirmed with the participant via an automated email.

Intervention 2: On completion of the online EOI, eligible prospective participants are asked to continue to complete a self-directed online enrolment process. They will be presented with an embedded short (1½ minute) video of an Aussie-FIT coach providing information about the Aussie-FIT program and this study that replicates the information provided in intervention 1 in the phone script. After viewing the video, participants will be asked to indicate that they understand three statements with essential information about Aussie-FIT and this study. Links to the 'Frequently Asked Questions' and 'Contact Us' sections of the Aussie-FIT website are provided in case the prospective participant has any questions or is unsure of anything. Next, they will be provided with a list of available dates/times to schedule their baseline appointment. On completion of this process all details will be confirmed with the participant via an automated email.

Index Type: Method of Recruitment

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Baseline appointment sign-up rate (number and percentage of EOIs that result in scheduled baseline appointments); baseline appointment attendance rate (number and percentage of baseline appointments attended of those scheduled).

Secondary: Resource-use and cost-per-participant. Phone call length will be recorded by Research Assistants to calculate total minutes and minutes-per- baseline appointment attended (i.e., resource use). Total cost, cost-per-program, and cost-per- baseline appointment attended will be calculated based on Research Assistant casual employment pay scale.

Acceptability of the enrolment process. This will be assessed using mixed methods at baseline, including: a) Likert scale question: "On a scale of 1 to 7, how easy was it for you to schedule today's enrolment appointment? (1 = very challenging, 7 = very easy)"; b) Free text response box: "Please provide any feedback you have on your experience scheduling today's enrolment appointment".

Analysis plans

For both SWAT groups, sign-up rate will be calculated by dividing the number of people who scheduled a baseline appointment by the number of eligible people who completed the EOI screening survey.

For both SWAT groups, attendance rate will be calculated by dividing the number of people who attended a baseline appointment by the number of eligible people who completed the EOI screening survey.

Differences between SWAT groups for sign-up and attendance rates will be assessed using Chi-squared test (or Fisher's Exact test).

Descriptive statistics of the secondary outcomes (phone call minutes, acceptability of enrolment) will be reported using mean (SD) or median (interquartile range) for both SWAT groups. Free text acceptability data will be analysed using content analysis. Cost difference between SWAT groups will be calculated from phone call minutes.

A finalised a-priori statistical analysis plan for the Aussie-FIT multi-State/Territory hybrid effectiveness-implementation RCT, which will include the analysis plans for this SWAT, will be posted on the Open Science Framework before the first participant is recruited.

Possible problems in implementing this SWAT

Researchers not adhering to the phone script (intervention 1). Internet coverage or technical issues with the study website, Qualtrics expression of interest form or embedded scheduling software.

We will use Standard Operating Procedures across study sites, research staff training, and regular check-ins with the project management team to ensure adherence to the enrolment protocol.

Aussie-FIT team contact details will be available on all promotional materials to help ensure that prospective participants can get in touch to enrol in the program regardless of their internet coverage or if technical issues arise. In addition, any men completing the online EOI who are randomised to the self-directed online enrolment (intervention 2) that do not schedule their online enrolment will be contacted within 7 working days by a researcher to progress their enrolment.

References

1. George ES, El Masri A, Kwasnicka D, et al. Effectiveness of Adult Health Promotion Interventions Delivered Through Professional Sport: Systematic Review and Meta-Analysis. *Sports Medicine* 2022;52(11):2637-55.

2. Healy P, Galvin S, Williamson PR, et al. Identifying trial recruitment uncertainties using a James Lind Alliance priority setting partnership—the PRioRiT_y (Prioritising recruitment in randomised trials) study. *Trials* 2018;19:147.
3. Kwasnicka D, Donnachie C, Thøgersen-Ntoumani C, et al. The Aussie-FIT process evaluation: feasibility and acceptability of a weight loss intervention for men, delivered in Australian Football League settings. *Psychology & Health* 2022;37(4):470-89.
4. Kwasnicka D, Ntoumanis N, Hunt K, et al. A gender-sensitised weight-loss and healthy living program for men with overweight and obesity in Australian Football League settings (Aussie-FIT): A pilot randomised controlled trial. *PLoS Medicine* 2020;17(8):e1003136.
5. Quested E, Kwasnicka D, Thøgersen-Ntoumani C, et al. Protocol for a gender-sensitised weight loss and healthy living programme for overweight and obese men delivered in Australian football league settings (Aussie-FIT): A feasibility and pilot randomised controlled trial. *BMJ Open* 2018;8(10):e022663.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Date of idea: 9/JAN/2023
Revisions made by:
Date of revisions: