RE: Query re SWAT Store 178 registration

Bethan Copsey <B.Copsey@leeds.ac.uk>   4 September 2023 at 14:05
To: Samuel Smith <S.Smith1@leeds.ac.uk>
Cc: "trial-forge-swat-centre@york.ac.uk" <trial-forge-swat-centre@york.ac.uk>

Hi Sam,

Thank you so much for this and for replying so quickly! That is really useful.

Best wishes,

Bethan

From: Samuel Smith <S.Smith1@leeds.ac.uk>
Sent: 04 September 2023 13:25
To: Bethan Copsey <B.Copsey@leeds.ac.uk>
Subject: RE: Query re SWAT Store 178 registration

Hi Bethan,

Thanks for this. I'll respond in order:

Detail on the design of the intervention is probably best found here: https://journals.sagepub.com/doi/full/10.1177/26320843211069530

The SWAT analysis plan currently in one of the protocols is as follows:

SWAT Population

The analysis of the SWAT will be conducted on all host trial participants who were randomised into the SWAT. All participants will be included in the analysis according to their randomised allocation for the SWAT, and regardless of non-adherence to intervention components or withdrawal from the host trial.

Questionnaire Response Rates and Completeness

Primary endpoint analysis:

Mixed effects logistic regression models will be used to analyse the differences in response rates at one month for each follow-up time point for each of the main effects (pre-notification vs. no pre-notification SMS and standard vs. non-standard SMS reminders). The analysis model will adjust for main trial allocation and previous SWAT allocation (where applicable).

Secondary endpoint analysis:

At each of the follow-up timepoints, questionnaire response will be summarised descriptively at 6 days after the administration of the questionnaire overall and by SMS pre-notification allocation. Questionnaire response summaries will also be presented at 11 days post-administration of the questionnaire for those receiving SMS reminders overall, by reminder type and by pre-notification SMS allocation. Questionnaire response will also be summarised at 1 month following questionnaire administration overall, by both SMS pre-notification and SMS reminder allocation.

Weighted and replicated logistic regression models will be used to analyse the difference in response rates between different embedded interventions (e.g. SMS pre-notification + standard reminder vs. no SMS pre-notification + non-standard reminder) adjusting for main trial allocation and previous SWAT allocation (where applicable).The number of days between questionnaire administration and completion will be summarised descriptively at both follow-up timepoints by SMS pre-notification allocation and SMS reminder allocation. The differences in time to return questionnaires for each of the main effects will be analysed using Cox Proportional Hazards regression, adjusting for main trial allocation and previous SWAT allocation (where applicable).

At each of the follow-up timepoints and for those who returned questionnaires, the proportion of non-mandatory questionnaire items missing and the proportion of non-mandatory questionnaire measures with complete data will be summarised at 6 days, 11 days and 1 month post questionnaire administration overall, by both SMS pre-notification allocation and SMS reminder allocation.

3. We have implemented the SWAT in a pilot trial (We Sure Can) hosted by Leeds CTRU, and then it'll be implemented again in a larger trial (ROSETA) also hosted by Leeds CTRU.

Best wishes

Sam

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From: Bethan Copsey <B.Copsey@leeds.ac.uk>
Sent: 04 September 2023 13:20
To: Samuel Smith <S.Smith1@leeds.ac.uk>
Subject: Query re SWAT Store 178 registration

Hi Sam,

As part of the Trial Forge SWAT Network, we have been looking at how we can improve the usability of the MRC SWAT Repository.

You have previously registered a SWAT (SWAT 178: Effects of SMS pre-notification and reminders on electronic questionnaire return using a sequential multiple assignment randomised trial (SMART) design) in the repository and I would welcome some additional information on this registration if possible please?

-     Is an example or any information on the design of the intervention available?

-     Was a statistical analysis plan or analysis section of the protocol written for the SWAT. If so could you provide a copy of this?

-     Are you aware of any replications of the SWAT? If so could you provide a reference/references?

I would be most grateful if you were able to provide any information here via email to trial-forge-swat-centre@ york.ac.uk, copying me in as this will be most helpful to our work.

Thank you,
Bethan

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