SAP: The effect of sending advanced notification to trial participants two weeks before outcome data collection to improve retention: an embedded randomised controlled trial in the WORKWELL trial

Authors of SAP

Sarah Rhodes, Sarah Cotterill, Alison Hammond, Denise Forshaw, Alexandra Haig, Chris Sutton.

Background

Many trials struggle with participant retention and completion of follow-up questionnaires. Recent research on the content of cover letters by Duncan and colleagues developed a theory-based response letter intervention using Michie's Theoretical Domains Framework (TDF) and associated Behaviour Change Techniques (BCTs) (1). Evidence on the effectiveness of this approach is still inconclusive and has been included as a SWAT idea in the PROMETHEUS project (SWAT24).

This SWAT will test a pre-notification communication sent two weeks before participants are due to be sent their 6-month follow-up questionnaire in the WORKWELL Trial(2), which is a pragmatic, multi-centre individually-randomised trial of job-retention vocational rehabilitation for employed people with inflammatory arthritis. The intervention to be tested is similar to that in SWAT 76(3), but will use a letter rather than a postcard in order to provide as consistent a form of pre-notification as possible between participants who opt to complete questionnaires by post and those who opt to complete electronically, whilst maintaining the patient choice of mode of communication.

The text in the pre-notification communication was informed by the theory and associated text used in the IQuad trial SWAT (SWAT 24)(4). The reminder letter (or email) will be personalised to include the (typed) name of the participant because there is some evidence that personalising may improve response rates in surveys.

Objective

To evaluate the effects of a pre-notification letter or email on completion and return of outcome questionnaires.

Design

A randomised trial embedded within the WORKWELL RCT.

Intervention: Pre-notification communication in advance of follow-up questionnaire. Participants who elect to complete follow-up questionnaires online will be sent a personalised pre-notification in an email two weeks prior to the mailing of this. Participants who elect to complete follow-up questionnaires in hard copy form and return by post will be sent a personalised pre-notification letter. Similar wording and layout will be used in the email and letter.

Control: No pre-notification communication.

Randomisation

Randomisation stratified by WORKWELL arm and preferred method of 6-month questionnaire receipt (electronic v postal).

Sample size

This is an embedded trial, restricted to a maximum of the size of the host trial, WORKWELL which is 240.

Timing of final analysis

It is anticipated that the analysis will be performed in Oct/Nov 2021, after the WORKWELL database is locked and a data abstract is provided to the SWAT statistician.

Timing of outcome measurement

The primary outcome is based on the 6-month outcome time-point for the WORKWELL trial, although this may be collected later than this time-point.

Confidence intervals and p-values

Confidence intervals will use 95% confidence. P-values will be presented where necessary, using a 5% significance level to focus interpretation, although confidence intervals will be the primary focus of interpretation,

Adherence and protocol deviations

Due to the Covid-19 pandemic, there were times when participants were offered the choice of switching to online rather than paper questionnaires with the explanation that this would be safer and easier. This meant that not all participants received their follow up questionnaire via their originally chosen method. The variable 'Chosen method of 6-month Questionnaire receipt' was used as a stratification variable and will be used for adjustment in the primary analysis. As a sensitivity analysis, the variable 'Method of 6-month questionnaire delivery' will be used instead.

Due to the Covid-19 pandemic, a number of participants did not return to work during their follow-up period as intended and therefore it was not relevant for them to complete the WLQ-25 questionnaire. This could have been due to furlough or participants who were shielding being unable to do their work from home. For this reason, there will be a deviation in the definition of the primary outcome measure; a response to the 6 month questionnaire that indicates that a person is 'not working' would be included as a valid response in the primary outcome.

Eligibility criteria

All participants within the WORKWELL trial, except those who have withdrawn or are known to have died prior to the planned mailing of the 6-month outcome questionnaire will be eligible. Participants will become part of the SWAT without additional recruitment or consent (over and above consent for WORKWELL).

Analysis population

The main analysis population will be all participants that were randomised as part of the SWAT, regardless of any SWAT protocol deviations.

Baseline characteristics

The following baseline characteristics will be reported by arm and overall

WORKWELL arm
Chosen method of 6-month Questionnaire receipt
Method of 6-month questionnaire delivery
Age
Sex
Ethnic group

Outcome measures

Primary:
- Valid response for WORKWELL trial primary outcome (yes/no) (i.e. usable outcome data for the primary outcome measure (either WLQ-25 total score(5)) obtained by any means, or response that indicates that the participant was not working at 6 months.

Secondary:
- Valid score for WLQ-25;
- Valid response for WORKWELL trial primary outcome (as above)(yes/no) *without reminder*
- Questionnaire returned(yes/no)
- Number of reminders sent (0 to 3 reminders);
- Time to response [or ceasing follow-up] (days);
- Cost of the intervention (£) per participant retailed
- Total cost (£) per participant retained.

Analysis

Baseline participant data, and the primary and secondary outcome measures will be summarised, using frequency (%), mean (SD) or median (IQR), as appropriate) both overall and by SWAT group allocation.

Comparison of the primary outcome between the pre-notification group and the no pre-notification group will use binary logistic regression, including the randomised group factor and adjusting for stratification variables (WORKWELL trial treatment allocation; chosen mode of response). Odds ratios and 95% confidence intervals for the between-groups difference in proportions completing the questionnaire will be estimated, and presented in conjunction with descriptive statistics of the number and percentage of respondents in each group. Analysis of the corresponding secondary outcome (valid response for WORKWELL trial primary outcome without reminder) will be performed using the same method.

Time to response (measured from day first sent) will be compared between the groups using Cox regression, adjusted for WORKWELL treatment allocation and chosen mode of response. A value of '1' will be added to all response times to avoid '0' values. The date of response is recorded as the date when the response first reached the CTU team (either at the University of Manchester or their home during periods of the COVID-19 pandemic). Data will be presented as a hazard ratio and related 95% confidence interval; median time to response in each group will also be presented. A Kaplan-Meier curve will also be produced.

Number of reminders by group will be presented as median(IQR). These will be compared using a Mann-Whitney U test.

For the analysis of the difference in costs per participant retained (i.e. with a valid response for WORKWELL trial primary outcome) between those randomised to pre-notification and those randomised to not be sent the pre-notification. Costs of the pre-notification intervention will include the direct costs of printing the pre-notification letter, envelopes and postage, and the cost of staff time spent administering the mail out (for example filling and labelling envelopes for those who choose to receive questionnaires by post, sending emails to those who choose to receive questionnaires electronically). We will present a crude analysis of the ratio of the estimated between-groups difference in costs, divided by the corresponding difference in proportions providing valid responses for WORKWELL trial primary outcome. However, as a secondary analysis, we have considered the relative costs of reminders, thus performing a fuller cost-effectiveness analysis. Within these costs, we have estimated the costs, telephone calls, printing and postage for reminders and reposting questionnaires, and of staff time to implement these.

Missing outcome data

Missing data on the primary outcome variable is not expected. Where data are missing, it will be assumed that the participant did not provide useable outcome data.

Missing covariate data

Data are not expected to be missing on the stratification variables that will be utilised in the primary analysis. Data may be missing on the variable 'response mode delivered' and this analysis will be based on available data only.

Sensitivity analyses

Adjustment for the 'response mode delivered' instead or 'chosen response mode'.
Analyses with no adjustment.

Subgroup analyses

Primary outcome and secondary outcomes with subgroups for the chosen response mode, implemented by adding an interaction between randomised group and chosen response mode.

Statistical Software

All analyses will be performed using Stata IC 14

Data manipulation

Derived variable needed for analysis	Variables required	Method
Valid 6-month WLQ Total score present	Response for each of the 25 items in the WLQ-25 questionnaire	See below
Valid response for WORKWELL trial primary outcome	Valid 6-month WLQ Total score present Not working at 6 months	1 if either 'Valid 6-month WLQ Total score present' =1 or 'Not working at 6 months' Valid response =1
Valid 6-month WLQ Total score without reminder	Valid 6-month WLQ Total score present Total Number of reminders for Q non-response	Replace 'Valid 6-month WLQ Total score present' with '0' if 'Total Number of reminders for Q non-response' >0
Time to valid response in days	Q returned Date Q first 'sent' Date Q returned	If ''Q returned'=1 Time = Date Q returned – date first sent + 1 If ''Valid response for WORKWELL trial primary outcome'=0 Time = maximum of time to Q returned Note: cases where questionnaire returned but response not valid will be censored at date of return
Costs		

Calculation of a valid WLQ-25 response

The WLQ-25 scale consists of 25 items; each item can be scored using a 5 point ordinal scale or a response of 'not part of my job/not applicable' can be given. The 25 items are divided into 4 subscales, Time management which has 5 items, Physical demands which has 6 items, Mental interpersonal demands which has 9 items and Output demands which has 5 items. A non-response is either a blank or a response of 'not part of my job/not applicable'. For a valid overall response a participant needs to have a response for 50% or more items on ALL of the 4 subscales.

Tables

Baseline characteristics (n(%)) by SWAT group allocation and overall

	Intervention N=	Control N=	Overall N=
WORKWELL arm A n(%) B n(%)			
Chosen method of 6-month Questionnaire receipt Postal n(%) Electronic n(%) Telephone n(%)			
Method of 6-month questionnaire delivery Postal n(%) Electronic n(%)			

Outcome data by SWAT group allocation

	Intervention N=	Control N=	Relative effect(95% CI)
PRIMARY Valid response for WORKWELL trial primary outcome Yes n(%) No n(%)			Odds ratio*
Valid total 6 month WLQ score Yes n(%) No n(%)			Odds ratio*
Valid response for WORKWELL trial primary outcome without reminder Yes n(%) No n(%)			Odds ratio*
Questionnaire returned Yes n(%) No n(%)			Odds ratio*
Number of reminders Median(IQR)			Median difference
Time to valid response for WORKWELL trial (days). Median			Hazard ratio*
Costs of intervention (£) Mean(SD)			Cost difference per participant retained

			Cost difference per participant retained
Total costs (£) Meandian(SDIQR)			

*Adjusted for WORKWELL arm and chosen method of delivery

Outcome data by SWAT group allocation, by chosen mode of delivery

	Intervention N=	Control N=	Relative effect(95% CI)
PRIMARY Valid response for WORKWELL trial primary outcome n(%) Postal Electronic Total			Odds ratio*
Valid total 6 month WLQ score n(%) Postal Electronic Total			Odds ratio*
Valid response for WORKWELL trial primary outcome without reminder n(%) Postal Electronic Total			Odds ratio*
Number of reminders Median(IQR) Postal Electronic Total			Difference in medians
Time to valid response for WORKWELL trial (days) Median Postal Electronic Total			Hazard ratio*
Cost of intervention (£) Mean (SD)			Cost difference per participant retained
Total Cost (£) Mean (SD)			Cost difference per participant retailed

*Adjusted for WORKWELL arm and chosen method of delivery

Figures

Kaplan Meier curve comparing 'Time to valid response' for WORKWELL trial primary outcome SWAT group allocation

References

1.	Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions. Annals of Behavioral Medicine. 2013;46(1):81-95.

2.	Hammond A, Sutton C, Cotterill S, Woodbridge S, O'Brien R, Radford K, et al. The effect on work presenteeism of job retention vocational rehabilitation compared to a written self-help work advice pack for employed people with inflammatory arthritis: protocol for a multi-centre randomised controlled trial (the WORKWELL trial). BMC Musculoskeletal Disorders. 2020;21(1):607.

3.	Treweek S, Gallant S, Anderson A. SWAT 76 evaluation: randomised evaluation of sending pre-notification cards to trial participants before a face-to-face primary outcome measurement to increase attendance [version 1; peer review: 1 approved]. F1000Research. 2021;10(84).

4.	Clarkson JE, Ramsay CR, Averley P, Bonetti D, Boyers D, Campbell L, et al. IQuaD dental trial; improving the quality of dentistry: a multicentre randomised controlled trial comparing oral hygiene advice and periodontal instrumentation for the prevention and management of periodontal disease in dentate adults attending dental primary care. BMC Oral Health. 2013;13(1):58.

5.	Lerner D, Amick BC, 3rd, Rogers WH, Malspeis S, Bungay K, Cynn D. The Work Limitations Questionnaire. Med Care. 2001;39(1):72-85.