

# **SWAT 89: Including a theoretically informed leaflet in a participant take-home pack of questionnaires to increase response rate**

## **Objective of this SWAT**

The joint aims of this study are:

- (a) To design a leaflet using a theory based behaviour change framework (anticipating the Theoretical Domains Framework) with the aim of maximising participant questionnaire response rates (achieved)
- (b) To further test this specific approach in a pragmatic setting to provide evidence of its applicability and effectiveness in respect of participant behaviour and adherence

Study area: Retention, Follow-up

Sample type: Participants

Estimated funding level needed: Unfunded

## **Background**

Ensuring adequately high levels of participant response rates is a common challenge for clinical trials.[1]

Although not conclusive, there is some evidence that interventions based on theoretical frameworks are more effective than interventions that are not theoretically informed.[2] Furthermore, the Medical Research Council highly recommends implementing behaviour change interventions based on theory when implementing complex interventions.[3] Since asking someone to return questionnaires is asking them to engage in a specific behaviour, behaviour change theories may inform successful methods to increase questionnaire responses. The Theoretical Domains Framework (TDF) is a tool for identifying theoretical targets for behaviour change interventions, which contains a collection of similar constructs drawn from many psychological models and put into theoretical domains (e.g. beliefs about consequences; social influence; knowledge).[4] Psychological constructs (e.g. attitude, self-efficacy, perceived control) within the domains can be modified using suitable behaviour change techniques (BCTs). These construct and domain appropriate BCTs are identifiable from BCT taxonomies.[5,6]

In a recent randomised study (SWAT 24), behaviour change interventions to encourage questionnaire completion were identified using the TDF and strategies known to influence salient domains for the target behaviour (returning the trial questionnaire) feasible to operationalise in a letter format (e.g. goal setting, persuasion) were incorporated into a cover letter sent out with trial questionnaires. The study showed that the return rate was significantly higher in those who received the theoretically informed letter than the group that received the original cover letter.[7]

This SWAT extends that research. It is being done with the PUrE randomised trial that is comparing different ways of treating lower pole kidney stones (ISRCTN98970319). The PUrE trial process is for participants to be issued with a participant pack containing the one and two week questionnaires, which they will take home with them following their intervention (the remaining questionnaires are issued from the trial office). In this SWAT, we aim to increase response rates to the PUrE questionnaires by including a theoretically informed leaflet in the participant pack that outlines the importance of questionnaire response. The content of this leaflet has been designed using an appropriate behavioural framework required for targeting the behavioural determinants relevant to this patient group as identified from evidence in the literature and input from a kidney stone patient group.

## **Interventions and comparators**

Intervention 1: Theoretically informed leaflet in the participant pack

Intervention 2: Generic compliments slip in the participant pack

Index Type: Participant Information

## **Method for allocating to intervention or comparator**

Randomisation

## **Outcome measures**

Primary: Participant response rates at one, two and twelve weeks post-intervention

Secondary:

## **Analysis plans**

## **Possible problems in implementing this SWAT**

Slow rate of recruitment to main study.

## **References**

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2. Ford ME, Havstad S, Vernon SW, Davis SD, Kroll D, Lamerato L, Swanson GM. Enhancing adherence among older African American men enrolled in a longitudinal cancer screening trial. *The Gerontologist*. 2006;46(4):545-550.
3. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*. 2008;337:a1655.
4. Michie S, Johnston M, Abraham C, et al. Making psychological theory useful for implementing evidence based practice. *Qual & Safety in Health Care*. 2005;14:26-33.
5. Michie S, Johnston M, Francis J, et al. From Theory to Intervention: Mapping Theoretically Derived Behavioural Determinants to Behaviour Change Techniques. *Applied Psychology: An International Review*. 2008, 57 (4), 660–680
6. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implementation Science*. 2012;7(1):1.
7. Duncan A, Bonetti D, Clarkson J, Ramsay C on behalf of the IQuaD study. Improving trial questionnaire response rates using behaviour change theory. *Trials*. 2015;16(suppl 2):P92.

## **Publications or presentations of this SWAT design**

## **Examples of the implementation of this SWAT**

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