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# Can the use of a theoretically informed covering letter for trial questionnaires improve participant response rates?

Beatriz Goulao<sup>1</sup>, Anne Duncan<sup>1</sup>, Patrick Fee<sup>2</sup>, Fiona McLaren-Neil<sup>2</sup>, Ruth Floate<sup>2</sup>, Fiona Ord<sup>2</sup>, Hazel Braid<sup>2</sup>, Debbie Bonetti<sup>2</sup>, Jan Clarkson<sup>2</sup>, Craig Ramsay<sup>1</sup>

<sup>1</sup>University of Aberdeen, Aberdeen, UK. <sup>2</sup>University of Dundee, Dundee, UK.



## Background

Low response rates to participant questionnaires in trials potentially put the validity and generalisability of the trial and its results in jeopardy. There was a lower than anticipated response rate to annual postal questionnaires in the NIHR HTA INTERVAL Dental Recalls Trial – a randomised controlled trial (RCT) based in dental primary care. A number of options to improve questionnaire response rates in trials have been reported, with limited evidence to support their success.

In response, a novel behaviour change intervention was developed to influence participant behaviour and encourage questionnaire return. This involved amending the covering letter included with postal questionnaires using the Theoretical Domains Framework (TDF) to identify theoretical targets for behaviour change interventions - the target behaviour being participant questionnaire return.

Evidence provided by the IQaD Trial study group demonstrated inclusion of a covering letter based on the TDF had a beneficial impact on the return rate of postal questionnaires<sup>1</sup>.

## Objectives

The aim of replicating this method within the INTERVAL trial in a randomised controlled trial was to:

1. Investigate if incorporating behaviour change techniques (BCTs) in the form of a theoretically informed covering letter would improve response rates to annual participant follow up postal questionnaires
2. Compare INTERVAL results with results from IQaD and contribute to evidence on general trial methodology research

## Methods

A behaviour change intervention was developed by a health psychologist in the form of a covering letter based on expert consensus using the TDF as a tool for identifying theoretical targets for behaviour change.

The cover letter issued with follow up postal questionnaires was revised to incorporate BCTs (prompt intention formation, provide information about others approval and support, provide general encouragement and information on consequences, and action planning) to encourage questionnaire return (Figures 1 and 2).

Figure 1: Example of text incorporating BCTs

This means your dentist has placed considerable trust in the patients they asked to join them in this research. Your dentist will not be able to fulfil their part in this study without the continued co-operation and participation of their patients.

... leaving the questionnaire out in the kitchen can serve as a reminder to complete it.

You may feel that one person's questionnaire is not that important in such a large study, but... every individual's contribution is needed to maintain the integrity of the end results.

This sub-study was designed as a randomised controlled trial, involving 1867 INTERVAL participants sent annual participant questionnaires at year 2 and 3 of follow up. Participants were randomly allocated to receive either a standard covering letter or a modified intervention letter based on the TDF. 1192 IQaD participants were sent annual questionnaires at year 1 and 2 of follow up and similarly randomised to receive a standard or intervention covering letter.

Response rates between the two groups were compared and the confidence interval of their difference calculated using Koopman's method. A fixed effect meta-analysis was calculated using the Mantel-Haenszel method.

## Acknowledgements

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Figure 2: Covering letters

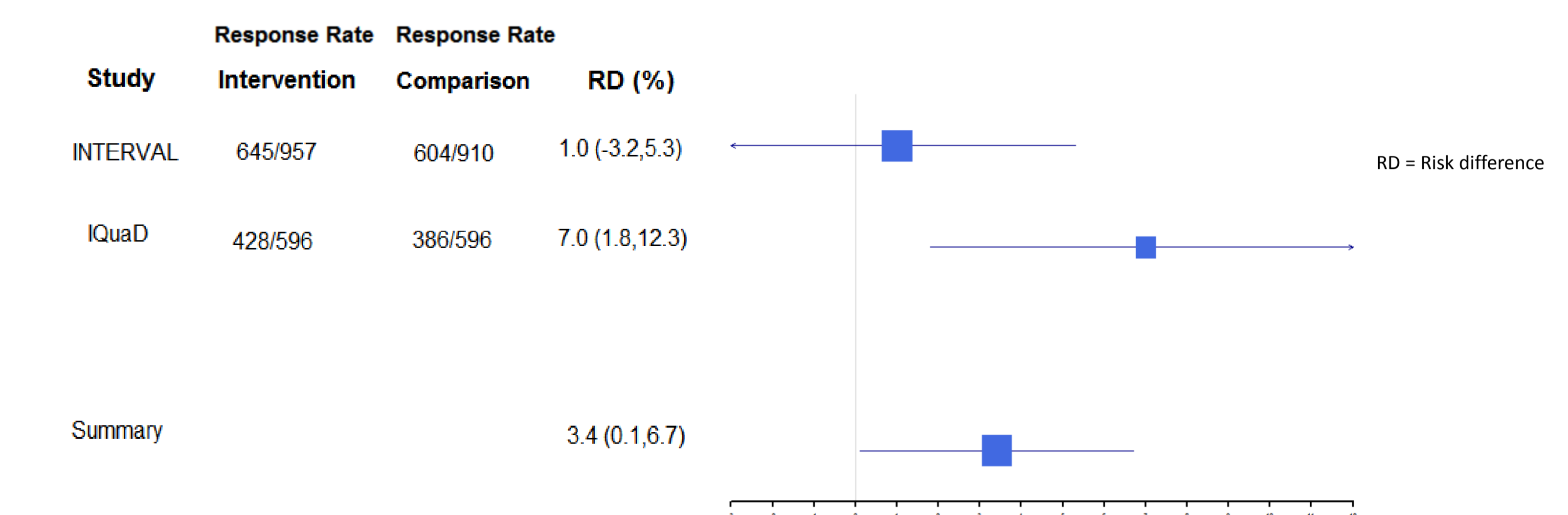


## Results

The overall response rate in INTERVAL was 67% for the cohort who received the theoretically informed cover letter and 66% in the control group. In IQaD the overall response rate in the intervention group was 72% and 65% in the control group.

On meta-analysis of results of INTERVAL and IQaD combined there is a risk difference of 3% in favour of the intervention (95% CI 0.1 – 6.7%). Results are displayed in a forest plot (Figure 3). The size of the square reflects the weight of the trial in the summary treatment effect. The vertical line indicates no treatment effect.

Figure 3: Forest plot of response rates to annual participant follow-up postal questionnaires between cohorts receiving a theoretically informed intervention letter and a standard covering letter in INTERVAL and IQaD trials



## Discussion

Inclusion of a covering letter based on the TDF with postal questionnaires resulted in an improvement in participant response rates in both the INTERVAL and IQaD trials.

Results of this study indicate that inclusion of a theoretically informed letter with postal questionnaires provides a cost effective method for improving participant response rates. It will be important to test this method of improving participant response rates to questionnaires in future clinical trials in different and similar contexts.

## References

1. Duncan A, Bonetti D, Clarkson J, Ramsay C. Improving trial questionnaire response rates using behaviour change theory. *Trials* 2015, 16(Suppl 2):P92

## Contact details

Patrick Fee  
School of Dentistry, University of Dundee, Park Place, Dundee, DD1 4HN  
Office: 01382 381711 Email [p.fee@dundee.ac.uk](mailto:p.fee@dundee.ac.uk)

