# CHANGING MODE OF FOLLOW-UP MID-STUDY DUE TO COVID-19 (ID BG1)

## BRIEF GUIDANCE SUMMARY

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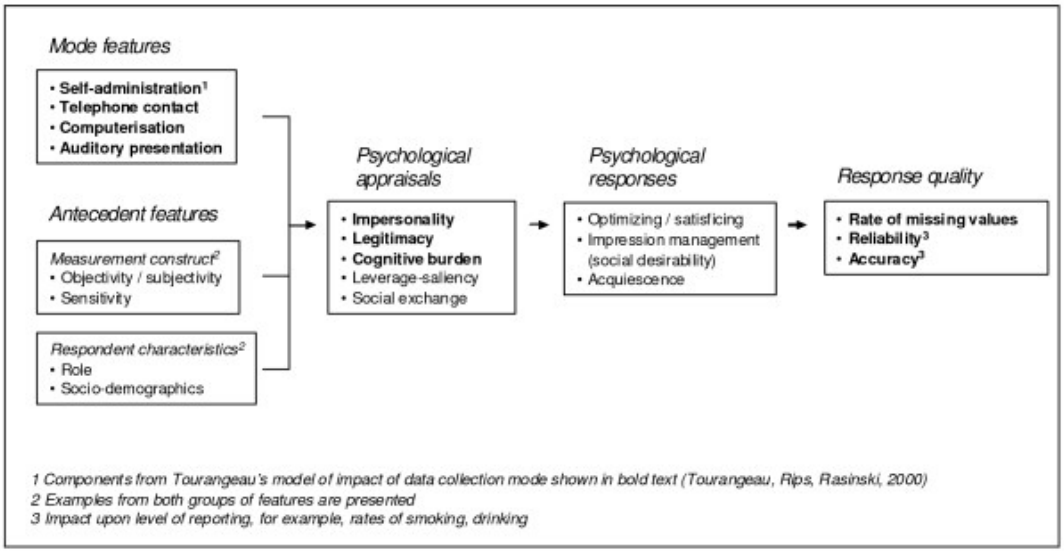
| **What is it?** | Brief guidance on the **potential impact on the measurement properties of the trial outcome if mode of follow-up is changed mid-study b**ecause of COVID-19. For example, from face-to-to face to telephone measurement. |
| **Who prepared it?** | Prof Kerry Hood, Director of the Centre for Trials Research, University of Cardiff, UK. |

## GUIDANCE

One area where changes have occurred in order to decrease the risk of exposure of patients in trials to infection and/or to decrease the burden on health services has been to change the mode of follow-up. This has often been from face to face to some sort of remote approach, for example telephone or web based assessment. This change needs to be considered as to its potential impact on the measurement properties of the outcome being assessed.

There can be two types of effect when changing mode – response rates and response changes. For this section we will focus on response changes as response rates are essentially dealt with under missing data. These response changes can be in terms of accuracy (do they report accurately on what has happened or how they feel?) and reliability (is this distributionally the same in terms of within person variability?).

A useful theoretical framework for things which affect these is summarised in the figure below.




Taken from: Applying an extended theoretical framework for data collection mode to health services research. Robling MR1, Ingledew DK, Greene G, Sayers A, Shaw C, Sander L, Russell IT, Williams JG, Hood K. BMC Health Serv Res. 2010 Jun 24;10:180. https://rdcu.be/b3P1X

In terms of studies which used mixed modes of data collection, the biggest factor for a difference in accuracy is between self and interviewer administrated questionnaires, followed by those where there is a difference in sensory stimuli (visual vs auditory usually). However these are still on average small for scales with more than one item. Overall for group based inference (rather than individual patients), impact is likely to be small, but would warrant some planned sensitivity analysis.

Taken from: Mode of data elicitation, acquisition and response to surveys: a systematic review. Hood K1, Robling M, Ingledew D, Gillespie D, Greene G, Ivins R, Russell I, Sayers A, Shaw C, Williams J. Health Technol Assess. 2012 May;16(27):1-162. https://www.journalslibrary.nihr.ac.uk/hta/hta16270/#/abstract

**Recommendation:** Undertake sensitivity analysis controlling for mode of data collection, by incorporating mode of data collection into your main analysis as a main effect and reviewing if this changes the result.

In terms of whether or not measures are distributionally the same, in general this is not a problem for group comparisons. However, if considering change over time within a person, where the mode has also changed, greater care is required. This can mainly been seen with an increased tendency for selection of first and last categories presented for questions presented aurally as opposed to visually.

**Recommendation:** Assess if there is a change in response distribution over time

One key additional element which needs to be considered is if there is likely to be an interaction between study arm and mode of data collection. There is far less evidence in this area, but given the theoretical model and the evidence shown in the review, if for example your intervention changed the psychological responses, then a more complex approach to the primary analysis may be required.

**Recommendations:**

- Assess the theoretical potential for the intervention to interact with mode in terms of the theoretical model. This is unlikely to occur in a blinded study and for unblinded trial could be achieved by reviewing the stated purpose of your intervention (for example a drug to enhance abstinence in problem drinkers implies that reporting lower drinking levels is socially derisable) or your logic model for a complex intervention on the pathway between intervention and effect.
- Undertake sensitivity analyses allowing for influence of proposed theoretical factors, by incorporating the mode of data collection into your primary analysis as both a main effect and an interaction with study arm. Further analysis could also include causal modelling.

## MORE INFORMATION

1. If you have any questions contact info@trialforge.org.