

User Guide to Expanded CONSORT Figure - fillable PDF®

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TABLE OF CONTENTS

Rationale, Purpose, and Overview of the Expanded CONSORT Figure	Page 2
<i>Expanded CONSORT Figure – fillable PDF</i>	Page 3
Example Figure	Page 4
Row-by-row instructions	Page 5
Frequently Asked Questions	Page 6
Key links, presentations, publications, and related references	Page 7

Expanded CONSORT Figure **Rationale, Purpose & Overview**

Rationale and Purpose

There are major problems with failure to replicate research findings. Contributing to this problem is a failure to report on factors related to external validity. The CONSORT flow diagram has improved reporting on variables related to internal validity, but it has very limited detail on issues related to external validity. A recent CONSORT update and other publications have called for more transparent reporting on external validity and context, and information regarding the sustainability of interventions.

The Expanded CONSORT Figure draws on theory, a prior meeting and recent recommendations for reporting factors related to external validity. It expands the basic CONSORT flow diagram for clinical trials to summarize external validity and contextual factors more concisely and transparently. It adds data about participation and representativeness at the levels of settings and staff, and about intervention sustainability after project support ends. This figure provides a method to address the representativeness, generalizability and sustainability of outcomes research more efficiently.

Overview

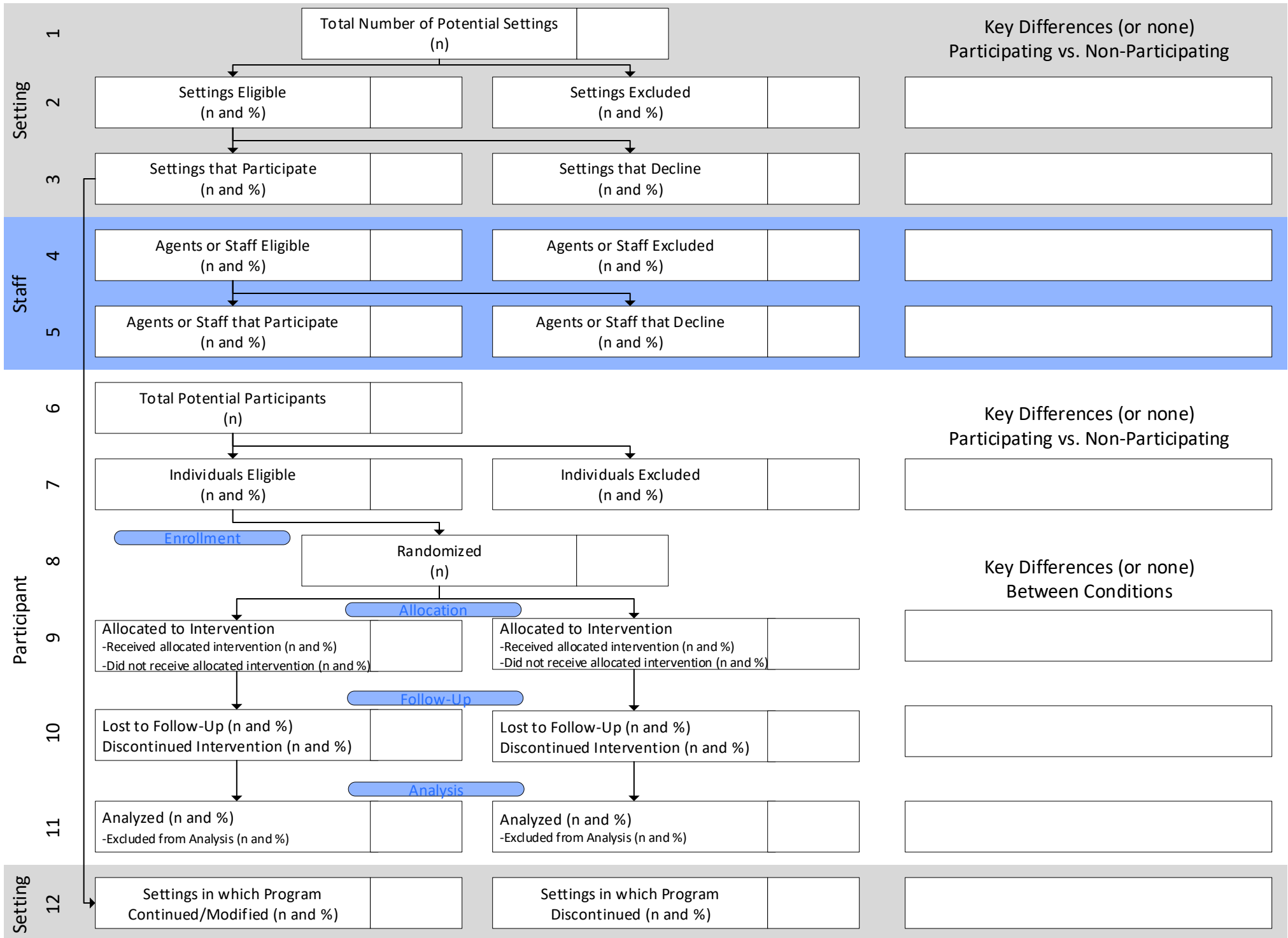
This guide provides step-by-step instructions (page 5) for completing the Expanded CONSORT Figure fillable PDF document (page 3) (referred to below as “The Figure”) as well as an illustrative example (page 4), a list of Frequently Asked Questions (page 6), and additional references for more information (page 7). The goal of this document, and related publications and references is to help those reporting, reading and evaluating journal articles to understand the importance of and how to transparently report the methodological and contextual factors regarding external validity and likely generalizability.

The Figure has fields to report on recruitment and participation at multiple levels: settings, staff, and participants, as well as intervention sustainability. For each item, the user enters the number and percent of units that were and were not offered participation, and the number and percent of those that decided to participate. In addition, the Figure allows space for researchers to report any differences between these groups, and to provide bullets related to qualitative findings about how and why these results occurred.

Finally, the Figure has fields to enter the number and percent of settings that continue (or modify) the intervention following the study assessment period when external funding is removed. The rationale for providing these multi-level data above is that they convey important information about the external validity of the study and generalizability of results.

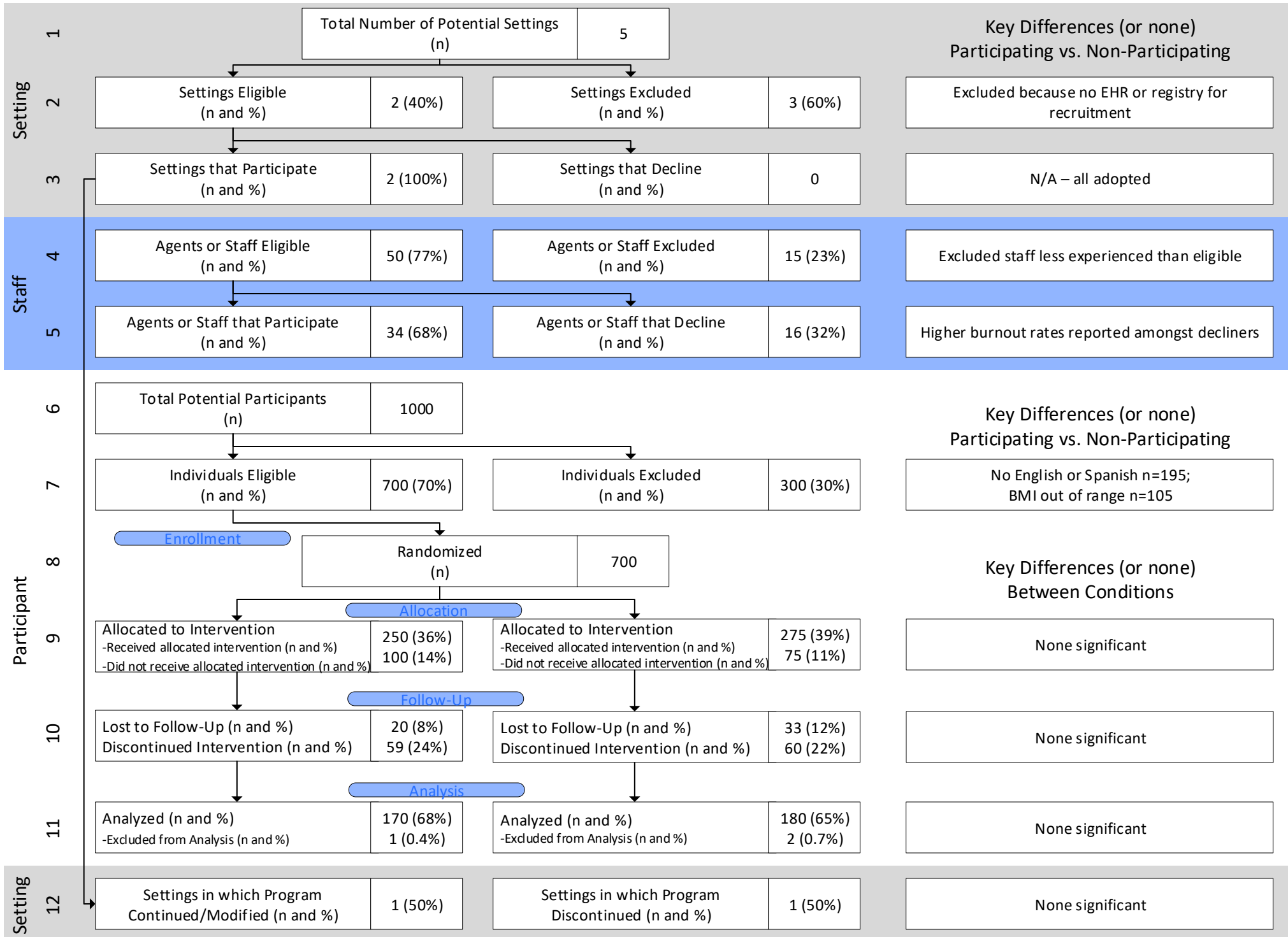
Expanded Consort Figure

Contextual Data and Participation Rates



Expanded Consort Figure

Contextual Data and Participation Rates



Row-by-Row instructions:

Beginning from the top of the document and working downward, complete the following steps to fill in and download or print the fillable Expanded CONSORT diagram.

Row 1.) (Settings)

At the top of the form, report the total number of potential settings (e.g. worksites, clinics, communities) that the project team could possibly have approached

Row 2.) (Settings)

Report the number and percent of settings that were invited to participate on the left

→ Left row 2 box: % = this number divided by row 1 box

Report the number and percent of settings that were excluded in the center

→ Center row 2 box: % = this number divided by row 1 box

On the right-hand side, briefly summarize key differences between settings invited and those not (see example below), or state 'no differences' or 'not analyzed'. Bullet points summarizing qualitative findings concerning reasons for exclusion can also be provided here.

Row 3.) (Settings)

Report the total number and percent of settings that agreed to participate on the left

→ Left row 3 box: % = this number divided by number in the left row 2 box

Report the number and percent of settings that declined in the center

→ Center row 3 box: % = this number divided by number in the left row 2 box

On the right-hand side, briefly summarize key differences between settings participating and those not (see example), or state 'no differences' or 'not analyzed'. Bullet points summarizing qualitative findings concerning reasons for non-participation can also be provided here.

Row 4.) (Staff)

Report the total number and percent of agents or staff that were found eligible to participate on the left

→ Left row 4 box: % = this number divided by the sum of both numbers in row 4

Report the number and percent of agents or staff that were excluded in the center

→ Center row 4 box: % = this number divided by the sum of both numbers in row 4

On the right-hand side, briefly summarize key differences between staff invited to participate and those not (see example below), or state 'no differences' or 'not analyzed'. Bullet points summarizing qualitative findings concerning reasons for exclusion can also be provided here.

Row 5.) (Staff)

Report the total number and percent of staff that agreed to participate on the left

→ Left row 5 box: % = this number divided by number in left row 4 box

Report the number and percent of staff that declined in the center

→ Center row 5 box: % = this number divided by number in left row 4 box

On the right-hand side, briefly summarize key differences between staff participating and those not (see example below), or state 'no differences' or 'not analyzed'. Bullet points summarizing qualitative findings concerning reasons for non-participation can also be provided here.

Row 6-10.) (standard CONSORT items)

In rows 6-10, complete the usual CONSORT information concerning potential participants, participants invited, randomized, present at follow-up, and analyzed. For further guidance see: <http://www.consort-statement.org/>

Row 11.) (Intervention Sustainability)

Report the total number and percent of settings that maintain or modify the intervention on the left

→ Left row 11 box: % = this number divided by number in left row 3 box

Report the number and percent of settings that discontinue the intervention

→ Center row 11 box: % = this number divided by number in left row 3 box

On the right-hand side, briefly summarize key differences between settings continuing (or modifying) the intervention and those not (see example below), or state 'no differences' or 'not analyzed'. Bullet points summarizing qualitative findings concerning reasons for non-continuation can also be provided here.

Frequently Asked Questions (last updated 3/03/2018)

Why doesn't the fillable PDF (page 3) save values when edited in my browser and then downloaded?

You must download the PDF before editing. Add values to the PDF in your Adobe reader and then save that file version or print it for future use.

Why do I need to complete the number of settings (or staff) that we decide to include and exclude?

These data help potential users judge applicability to their own settings and researchers to judge the likely generalizability of findings across settings (or types of staff)

What if I do not know the number of potentially eligible settings, staff or participants?

It is still important to estimate these 'denominator numbers' (Gaglio and Glasgow, 2018; Glasgow et al, 2018). You should give your best guess in the Figure, and then provide an upper and lower bound for this denominator in the text in the same way that economists conduct sensitivity analyses (Ritzwoller, D., Sukhanova, A., and Glasgow, R. 2009)

What if I do not have any data or analyses on differences between participating and non-participating units?

Simply report 'Data not collected (or not analyzed)'. We understand that it is not possible or relevant to collect data on all issues in most studies, but it is helpful to know if there were no differences between participating and non-participating units, or if no data are available.

Why is it important to report qualitative data in this Figure?

Qualitative data are important to help understand how and why results come about that are seldom if ever available from quantitative surveys. If you do not have the resources to conduct formal qualitative data collection and analyses, consider either just contacting few non-participating units to obtain a general idea of their reasons, or simply report 'no qualitative data'

What do I do if there is not enough room to describe information in the right-hand side of the Figure on differences or qualitative findings?

The right-hand side is only intended to 'signal' that differences in representativeness exist, or that there is information on why these results were found. Brief bullet point summaries are fine here to keep all the information on one page. Information that is more detailed can be provided in the text, an appendix, a URL link, or a separate manuscript depending upon the situation.

References and Presentation That Directly Explain, Illustrate or Discuss the Expanded CONSORT Figure

1. Glasgow, R., Huebschmann, A., Brownson, R. (2018) Expanding the CONSORT Figure: Increasing Transparency in Reporting on External Validity. *Amer J Prev Med*, (revision submitted).
2. Glasgow, R., Huebschmann, A. (June 2017) *Expanded CONSORT Figure for Planning and Reporting D&I Research*. Plenary presentation at Getting Dissemination and Implementation Science Ideas Funded – An Interactive, Pragmatic Workshop, Aurora, CO.
3. Huebschmann, A., Leavitt, I., Glasgow, R. (2018) External Validity. *Ann Rev Public Health*. (under review)
4. Kwan, B., Chadha, S., Hamer, M., Spagnolo, D., & Kee, S. (2017). Mixed methods evaluation of a collaborative care implementation using RE-AIM. *Families, Systems & Health : The Journal of Collaborative Family Healthcare*, 35(3), 295-307.

Supporting References and Resources for More Information

1. Altman, Schulz, Moher, Egger, Davidoff, Elbourne, . . . Lang. (2001). The revised CONSORT statement for reporting randomized trials: Explanation and elaboration. *Annals of Internal Medicine*, 134(8), 663-94.
2. Boutron, I., Altman, D., Moher, D., Schulz, K., & Ravaud, P. (2017). CONSORT Statement for Randomized Trials of Nonpharmacologic Treatments: A 2017 Update and a CONSORT Extension for Nonpharmacologic Trial Abstracts. *Annals of Internal Medicine*, 167(1), 40-47.
3. Chambers, D., Glasgow, R., & Stange, K. (2013). The dynamic sustainability framework: Addressing the paradox of sustainment amid ongoing change. *Implementation Science : IS*, 8, 117.
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11. Pinnock, Barwick, Carpenter, Eldridge, Grandes, Griffiths, . . . Taylor. (2017). Standards for Reporting Implementation Studies (StaRI) Statement. *BMJ*, 356 , Article i6795. (2017).
12. Tomoia-Cotisel, A., Scammon, D., Waitzman, N., Cronholm, P., Halladay, J., Driscoll, D., . . . Stange, K. (2013). Context matters: The experience of 14 research teams in systematically reporting contextual factors important for practice change. *Annals of Family Medicine*, 11 Suppl 1, S115-23.
13. www.re-aim.org
14. University of Colorado Denver, ACCORDS D&I Program - <https://goo.gl/DmGbGc>