Ask what matters to me. Collecting meaningful and acceptable outcome measures with people from under-researched groups: a scoping review protocol

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Background

Clinical trial research increasingly demonstrates that participants do not understand outcome measures and do not agree with choices of primary outcome in terms of importance. Often outcomes that are less important to the patients dominate the study design (Treweek et al., 2022, Rahimi et al., 2010). It has also been noted in a commentary on 'bad health research' and the usefulness of clinical trials, that important questions about outcomes that were important to decision-makers, and the end-users of research, may not have been asked (Pirosca et al., 2022).

One of the consequences of the failure to take account of patients' perspectives when designing research is that clinical trial outcomes fail to translate into benefits to patients (Heneghan et al., 2017). Additionally, there is concern that when Patient Reported Outcome Measures are designed they may not take account of minority populations, potentially contributing to widening inequalities (Long et al., 2022). Such factors are likely to be compounded in complex community-based intervention studies which have multiple outcome measures.

In our community-based research (for example Hanson et al. (2016)), and community listening project run by the NIHA co-production partnership (https://healthyageingnorwich.com/co-production/), we found that multiple outcome measures are neither comprehensible nor meaningful to participants. This is particularly apparent in under-researched groups, where body changes such as feeling less breathless and being able to tighten a belt, and non-health benefits, e.g., saving money and a nice-smelling house from quitting smoking are more meaningful than common measures (e.g., clinical) used by researchers. It is increasingly recognised that participant reported outcome data from clinical trials should be generated in such a way as to support meaningful treatment options (Snyder et al., 2022). However, our initial scoping of the literature indicates a lack of evidence on meaningful outcome measures for people who are often under-researched and more often also have the greatest health need.

The culmination of these issues is waste (predominantly through study attrition), loss of goodwill from communities that might have expressed interest in being involved in research and commissioning decisions informed by evidence not relevant to end users. Additionally, unnecessary barriers are created for people with poorer literacy levels and those under-represented in research. It is unethical to ask people to complete outcome measures that are not understood, as people should be fully informed before they consent (and this would include what is being measured, and why), but researchers ask potential participants to complete a host of measures that neither matter, nor are meaningful to them. In conclusion, poorly understood outcome measures are a likely reason for under-engagement of people from marginalised communities, who also have the greatest health needs, therefore having the potential to contribute to widening inequalities.

Rather than solely focusing on what is wrong with people and communities (e.g., disease risk and profile), theoretically this review will use the principles of Salutogenesis (what makes people well, what gives people hope) which reflects the strengths in communities (Hopkins and Rippon, 2015). This approach empowers people to determine what matters to them. Empowering people and communities (such as Asset Based Community Development (ABCD), Cormac Russell) is increasingly successful in improving health in under-served communities (Russell, 2022).

The questions that this scoping review seeks to understand

1. What is known about patient-centred holistic health, wellbeing and social outcome measures in community-based research in under-researched groups?
2. Using the principles of 'Salutogenesis' (what makes people well, 'what matters to me'), how is this accounted for in community-based research and included as outcomes?
3. Is there evidence that some research methods (such as creative methods) have greater success than others in identifying outcome measures that are perceived as more important to participants? And is there evidence of this being different to researchers and clinicians?
4. How are decisions made about outcome measures in community-based research with under-researched groups?

Methods

Scoping reviews aim to better understand a body of literature and to inform practice in the field (Munn et al., 2018). Our population of interest, under researched groups, is not easily defined and requires a broad review of the literature, again indicating scoping review methods. The methods for this review are guided by Joanna Briggs Institute (Peters et al., 2021), including the reporting used PRISMA-ScR (Tricco et al., 2018). Specifically:

Participants

This review will include studies on adults (18 years and older). It will focus on under-researched groups guided by the National Institute of Health Research Guidance for under-served groups in clinical research. We will use the examples of under-served groups as listed in the NIHR INCLUDE guidance as a starting point (https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435).

Concept

This review will include studies that explore the concept of asset-based approaches, salutogenesis (what makes us well) and sense of coherence in community based research as detailed in work such as Heads, hands and heart (Hopkins and Rippon, 2015). We will seek to understand how outcome measures are decided and used and suggestions by the authors of the papers on what are meaningful and acceptable outcomes for participants and researchers in community-based research.

Context

Studies will be community-based. This will not include prisons, care or other residential settings where people are not free-living in the community. We are also interested in the methods used to include under-researched groups in community-based research. Because we aim to understand research that can be applied in a UK context, we will only include research from sources that broadly reflect a UK understanding of community-based research. We will therefore only include studies from G7 countries, the European Union, Australia and New Zealand. This decision is not attributing a hierarchy to other nations (Khan et al., 2022).

Search strategy

Collaborating with an information specialist, the retrieval of records will be conducted from three key databases: Medline Ultimate, PsycINFO, and Scopus. The search strategy will entail the identification of potentially relevant scholarly articles employing terms related to patient-reported outcomes, health, and underrepresented demographic groups. To align with contemporary research trends emphasising asset-based and salutogenic approaches within the realms of health, wellbeing, and social care, the searches will be limited to papers published between 2013 and the present day.

In addition, forward and backward citation tracking will be employed to identify significant papers not included in the original search. Grey literature will also be searched, utilising platforms such as Google, to ensure a comprehensive inclusion of relevant materials beyond the confines of traditional academic databases.

Isolating relevant studies and sources

Following the search, all identified citations will be collated and uploaded into Endnote X9 (Clarivate Analytics, PA, USA) and duplicates removed. We will firstly conduct a pilot test, whereby AS and SH will independently screen the titles and abstracts of a minimum of 40 papers to ensure agreement on inclusion for full text review. When we are confident that we have a common and consistent understanding on this, the titles and abstracts of all the remaining papers will be screened for inclusion by either AS or SH. Texts of the remaining papers will then be read in full by either AS or SH to establish whether they meet our inclusion criteria. The reasons for not including full texts in the review will be reported. Those that we are unsure about will be discussed and if we remain unsure, will be checked by a third reviewer (WH). See Table 1 for Inclusion and Exclusion criteria.

Table 1: Inclusion and Exclusion Criteria

Included	**Excluded**
Adults over the age of 18 years of age	Information about those under 18. Where the study is mixed, only adult data will be extracted.
Adults free living in the community	
Studies conducted in G7 countries, European Union, Australia and New Zealand	
	Populations not in under-researched groups (see text above)
Studies that include displaced people in G7 countries, The European Union, Australia and New Zealand	Studies of people displaced to countries other than those in our included list
	Studies about Covid-19
	Studies about dental and oral health
	Studies on military veterans or people serving in the military
	Studies on maternal health
	Studies on workplace health
	Studies without qualitative data

Data extraction

Data will be extracted into a data extraction sheet, developed a-priori. This will include: i) Profile and number of participants, specifically socio-economic information; ii) Overview of the study iii) Evidence of creative access to participants iv) Study type (including data collection and analysis methods, evidence of creative methods) v) Evidence of co-development (e.g., Public and Patient Involvement – PPI and peer/community workers); vi) Who collected data (e.g., use of community researchers); vii) Outcome as described in the paper; viii) Evidence of 'what makes people well' and 'what is important to people' (as described in the paper) ix) Suggestions from the authors on outcome measures x) Quotes (data).

To ensure reliability and consistency, for each paper either AS or SH will extract data, with a second reviewer (WH, AW or GU) checking data extraction. Differences will be noted and then discussed to reach agreement between the two authors. A third author will be involved to check again and reach agreement if there continues to be differences. Should the review become unmanageable due to the volume of identified papers, an extra experienced reviewer will be brought into the team.

Data Analysis and Presentation

A narrative summary will accompany the tabulated results and will describe how the results relate to the review's research questions. In addition, these results will be sense-checked by members of the public from three community organisations who are representative of the populations being researched in this scoping review (Pollock et al., 2022). This will be assisted by GU, who runs a community-based group. Godwin has helped design this study and will also check and analyse the data as part of the research team.

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Conflicts of interest

The authors declare no conflict of interest.

References

HANSON, S., GUELL, C. & JONES, A. 2016. Walking groups in socioeconomically deprived communities: A qualitative study using photo elicitation. *Health and Place,* 39**,** 26-33.

HENEGHAN, C., GOLDACRE, B. & MAHTANI, K. R. 2017. Why clinical trial outcomes fail to translate into benefits for patients. *Trials,* 18**,** 122.

HOPKINS, T. & RIPPON, S. 2015. Head, hands and heart: asset-based approaches in health care. *London: The Health Foundation*.

KHAN, T., ABIMBOLA, S., KYOBUTUNGI, C. & PAI, M. 2022. How we classify countries and people-and why it matters. *BMJ Glob Health,* 7.

LONG, C., BERES, L. K., WU, A. W. & GILADI, A. M. 2022. Patient-level barriers and facilitators to completion of patient-reported outcomes measures. *Quality of Life Research,* 31**,** 1711-1718.

MUNN, Z., PETERS, M. D., STERN, C., TUFANARU, C., MCARTHUR, A. & AROMATARIS, E. 2018. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. *BMC medical research methodology,* 18**,** 1-7.

PETERS, M. D., MARNIE, C., TRICCO, A. C., POLLOCK, D., MUNN, Z., ALEXANDER, L., MCINERNEY, P., GODFREY, C. M. & KHALIL, H. 2021. Updated methodological guidance for the conduct of scoping reviews. *JBI evidence implementation,* 19**,** 3-10.

PIROSCA, S., SHIELY, F., CLARKE, M. & TREWEEK, S. 2022. Tolerating bad health research: the continuing scandal. *Trials,* 23**,** 458.

POLLOCK, D., ALEXANDER, L., MUNN, Z., PETERS, M. D. J., KHALIL, H., GODFREY, C. M., MCINERNEY, P., SYNNOT, A. & TRICCO, A. C. 2022. Moving from consultation to co-creation with knowledge users in scoping reviews: guidance from the JBI Scoping Review Methodology Group. *JBI Evidence Synthesis,* 20**,** 969-979.

RAHIMI, K., MALHOTRA, A., BANNING, A. P. & JENKINSON, C. 2010. Outcome selection and role of patient reported outcomes in contemporary cardiovascular trials: systematic review. *Bmj,* 341.

RUSSELL, C. 2022. Understanding ground-up community development from a practice perspective. *Lifestyle Medicine,* 3**,** e69.

SNYDER, C., CROSSNOHERE, N., KING, M., REEVE, B. B., BOTTOMLEY, A., CALVERT, M., THORNER, E., WU, A. W. & BRUNDAGE, M. 2022. The PROTEUS-Trials Consortium: Optimizing the use of patient-reported outcomes in clinical trials. *Clinical Trials,* 19**,** 277-284.

TREWEEK, S., MIYAKODA, V., BURKE, D. & SHIELY, F. 2022. Getting it wrong most of the time? Comparing trialists' choice of primary outcome with what patients and health professionals want. *Trials,* 23**,** 537.

TRICCO, A. C., LILLIE, E., ZARIN, W., O'BRIEN, K. K., COLQUHOUN, H., LEVAC, D., MOHER, D., PETERS, M. D., HORSLEY, T. & WEEKS, L. 2018. PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation. *Annals of internal medicine,* 169**,** 467-473.