STEPUP

STEP UP: Strategies for Trialists to promote Equal Participation in clinical trials for Under-served Populations

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Background

Trials should include everyone in the population that could benefit from the intervention being tested

Several frameworks have been developed to help researchers think about the barriers to inclusion of particular under-served groups when designing a trial

- **INCLUDE ethnicity framework, socioeconomic disadvantage framework and the capacity to consent framework**
- **Equality impact assessments**

Lack of practical guidance on how to implement these frameworks

Methods

Collaborators from the MRC-NIHR-TMRP inclusivity group and via UKCRC

Five project phases:

- Scoping review: A broad literature review to identify existing strategies
- ‘Roundtable’ discussions: Gathering insights from various stakeholders
- Trial redesign: Applying identified strategies to three real-world trials
- Interviews: Exploring implementation challenges and facilitators
- Guidance development: Collating findings into the STEP UP guidance

Public contributors and the ACCESS team provided valuable input throughout the project.

Biggs, K., et al. "Time to STEP UP: methods and findings from the development of guidance to help researchers design inclusive clinical trials." BMC Medical Research Methodology 24.1 (2024): 227 (https://doi.org/10.1186/s12874-024-02342-y).

Results

Over 40 experts contributed to the ACCESS project - patients and the public, clinicians, NHS research staff, trialists and other academics

The scoping review identified several strategies being used to improve inclusion

- Mostly around recruitment settings
- Little/no evaluation of these strategies

The 'roundtable' discussions identified additional strategies being used across the UK and Ireland

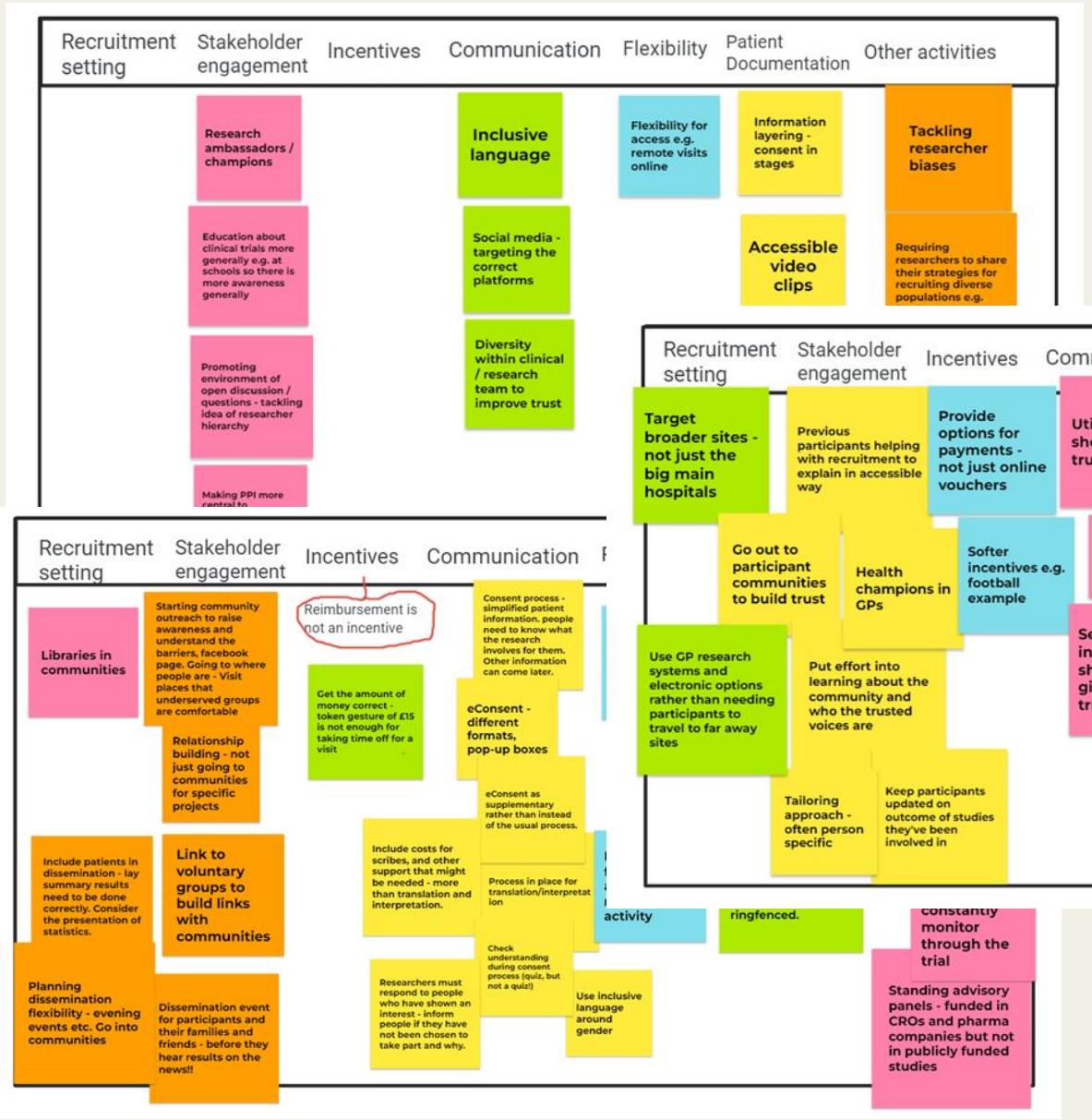
These strategies were used to redesign existing trials by applying one of the three INCLUDE frameworks to one trial each, leading to key recommendations for the guidance.

Key facilitators identified in interviews:

- Funders requesting information on inclusion,
- Having time and funding
- Dedicated staff
- Flexibility in trial protocols
- Considering inclusion of under-served groups at the design stages.

Biggs K, Dix C, Shiely F et al. Effective interventions to increase representation of under-served groups in randomised trials in UK and Ireland: a scoping literature review [version 1; peer review: 2 approved]. NIHR Open Res 2024, 4:12 (https://doi.org/10.3310/nihropenres.13524.1)

Roundtable ‘Jamboards’



Trial redesign

	Stroke trial Meeting date: 16/06/2022	Depression trial Meeting date: 02/09/2022	Diabetes trial Meeting date: 03/10/2022
Population; Recruitment setting	Care home residents with confirmed or suspected stroke; Care homes.	Adults with depression who scored ≥ 10 on the Patient Health Questionnaire-9 (PHQ-9); Primary care/General Practices (GPs)	Patients with Diabetic Peripheral Neuropathic Pain (DPNP); Secondary care/hospitals
Intervention	Occupation therapy package was delivered to residents and care home staff.	Two intervention groups: two types of online Cognitive Behavioural Therapy.	Six sequences consisting of 3 drug pathways.
Comparator	Usual care.	Usual care by their GP.	Placebo.
Outcome	Barthel Index score (assesses dependency).	Depression severity and symptomatology as measured by a validated self-report measure (PHQ-9).	7-day average 24-hour pain (evaluated at patient level) on an 11-point rating scale
INCLUDE framework	Impaired capacity to consent framework.	Socio-economic disadvantage framework.	Ethnicity framework.

1 Recruitment and setting

Trial teams must accurately reflect patient populations in clinical trials.

They may choose to:

- **Conduct equality impact assessments**
- **Include sites located in under-served areas**
- **Use baseline data to inform ongoing site selection**
- **Modify inclusion criteria**

> How could implicit eligibility criteria, such as the expectation to speak English, impact diverse participation in trials?

Budget considerations

- Time to undertake INCLUDE frameworks or Equality Impact Assessments
- Time for collecting data from sites to determine population served
- Several strategies may need costing
  - Online, postal, targeted advertising, flyers, community visits
- Larger samples, and longer recruitment, needed for powered sub-group analysis
- Additional sites might be needed to recruit a more diverse sample
  - May not be ‘research ready’
  - More time might be needed for set up
- More time for community-based strategies
  - Training, recruiting, attending events
- Recruitment might take longer for underserved groups
  - The consent visit
  - The whole recruitment period
- Time for monitoring recruitment and retention

2 Stakeholder engagement

Working with people who have lived experiences of conditions is invaluable, but trial teams should also strive to engage with groups who are under-served by research.

They may choose to:

- **Include the perspectives of under-served groups in patient and public involvement initiatives**
- **Build relationships with communities under-served by research**

> How could implicit eligibility criteria, such as the expectation to speak English, impact diverse participation in trials?

Budget considerations:

- One or more co-applicants, +++ to capture diversity
- Covering care costs, accommodation for meetings split over two days
- Room hire and refreshments for community venues
- Promotional materials in easy-read or translated
- Co-production costs – more meetings, more PPI payments
- Additional input into analysis, reporting, and dissemination

3 Communication

Trial teams should use effective communication to build trusting relationships with under-served groups and to reduce power balances.

They may choose to:

- **Use simple, easy-to-understand language**
- **Tailor communications to the needs and preferences of different groups**
- **Use videos to supplement clinical trial materials**
- **Ensure interpreters are available to translate throughout the trial**
- **Share trial outcomes with participants**

> Would the use of 'easy-read' materials help encourage greater participation from people with learning disabilities?

Budget considerations

- Costs for producing tailored communication, translation
- Costs for making videos for patient information, intervention delivery etc
- Increased communication may need increased staff time
- Additional documents for keeping in touch (retention) in a range of formats and languages
- Additional approval time for new documents or changes during the trial
- Disseminating findings in different formats
- Dissemination via community organisations – costs for them or for visits

4 Flexibility

Trial teams should try to implement as much flexibility as possible throughout the trial.

They may choose to:

- **Provide flexibility in recruitment methods**
- **Consider alternative delivery methods**
- **Be flexible with times for clinic visits**
- **Consider alternative incentives**

> Could the trial intervention be delivered more locally to the participant, such as in community venues or local GPs?

Budget considerations

- Several strategies for engagement may need costing
  - Online, postal, calls, clinic visits, home visits
  - Increased staff time
    - Study managers
    - Data managers
    - Site staff
- Costs for incentives (different types)

5 Researcher training and hiring strategies

Trial teams should all have a thorough understanding of the impact of racism, prejudice, and ableism in healthcare.

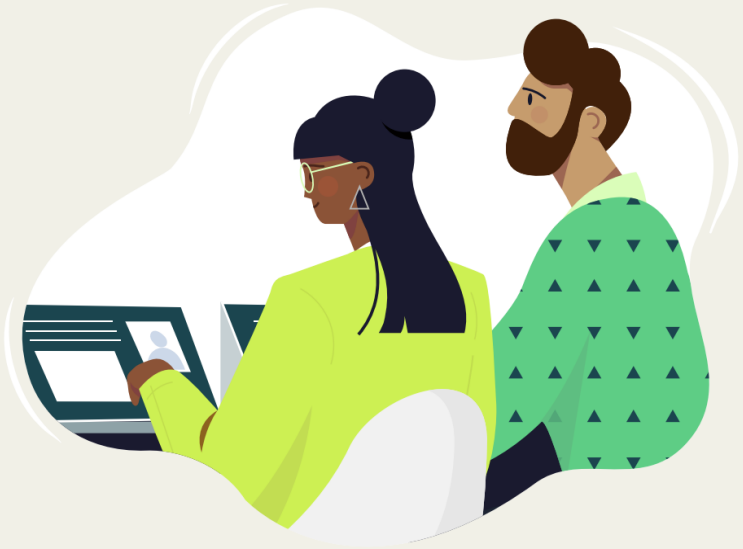
They may choose to:

- **Be provided with cultural competency training**
- **Have a diverse range of backgrounds**
- **Be confident in communicating with patients who have disabilities**

> How can trial teams build on their knowledge of racism to reduce implicit bias?

Budget considerations

- Co-applicant
- Training for trial team and site staff
- Community researcher
- Time to build relationships and time to recruit community researchers



6 Data collection

Trial teams should ensure data is collected and shared in a way that promotes flexibility and trust with under-served groups.

They may choose to:

- **Collect demographic data of potential, lost, and current participants**
- **Identify trends to better understand why people from under-served groups drop out**
- **Allow different methods of data collection throughout the trial**
- **Allow for proxy completion to be carried out by friends or relatives**
- **Consider sub-group analysis**

> How can alternative methods of data collection enable people with disabilities to participate in clinical trials?

Budgeting considerations

- Staff time to develop/amend data collection forms and databases
- Recruiting, training and paying interpreters
- Translation of data collection materials
- Costs linked to in person data collection in the community/home
  - Equipment for home data collection
- Costs linked to clinic visits
  - Childcare or respite care costs for visits
  - Travel costs
  - Compensation for loss of earnings
- Additional time for exploratory analysis around participant demographics/intersectionality

Next steps

- These strategies need to be tested – potential methodology projects
  - INVITE RfPB grant led by Kirsty Roberts at University of Bristol
  - SWATs can be designed, or adapted from existing ones
    - SWAT 15 – use of videos
    - SWAT 205 – use of translated videos
  - QuniteT Recruitment Interventions can be adapted to focus on under-served groups
  - Simple language in ‘consent conversations’

Related links

- STEP UP guidance – https://step-up-clinical-trials.co.uk/
- See the 'Trial Forge Guidance 3: randomised trials and how to recruit and retain individuals from ethnic minority groups—practical guidance to support better practice' for a worked example: https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-022-06553-w
- See the 'Budgeting for Inclusion' section of the Equality, Diversity and Inclusion Toolkit from the Research Support Service for more details: https://www.rssleicesterresources.org.uk/budgeting?tags=EDI
- SWAT repository: https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/SWATSWARInformation/Repositories/SWATStore/
- QuinteT recruitment intervention: https://pmc.ncbi.nlm.nih.gov/articles/PMC4898358/

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Any questions?

https://step-up-clinical-trials.co.uk/

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