Randomised controlled trials of social interventions

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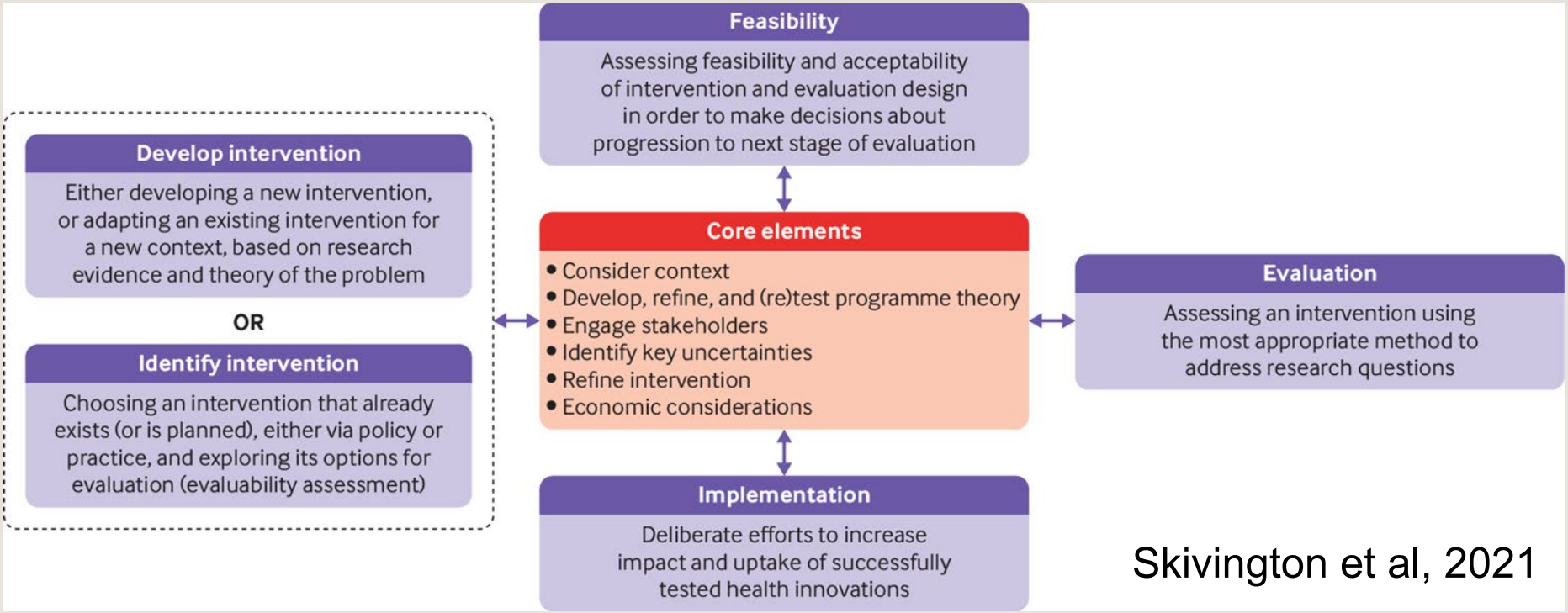
Webinar plan

- Introduction to randomised controlled trials of social interventions
- Ethical issues
- Recruitment, retention and data collection
- Using lived experience to inform trial methods and procedures
- Experiences of trial management and site liaison

Social interventions

- Social interventions:
  - Are purposeful actions taken by a worker, team or organisation to address social issues
  - Aim to improve wellbeing or social outcomes such as loneliness or social connections
  - Are not primarily medical or psychological, though may include elements (e.g. psychosocial group interventions)
  - Are often community-based, involve a wide range of services and can be inherently complex

Evaluation of complex interventions

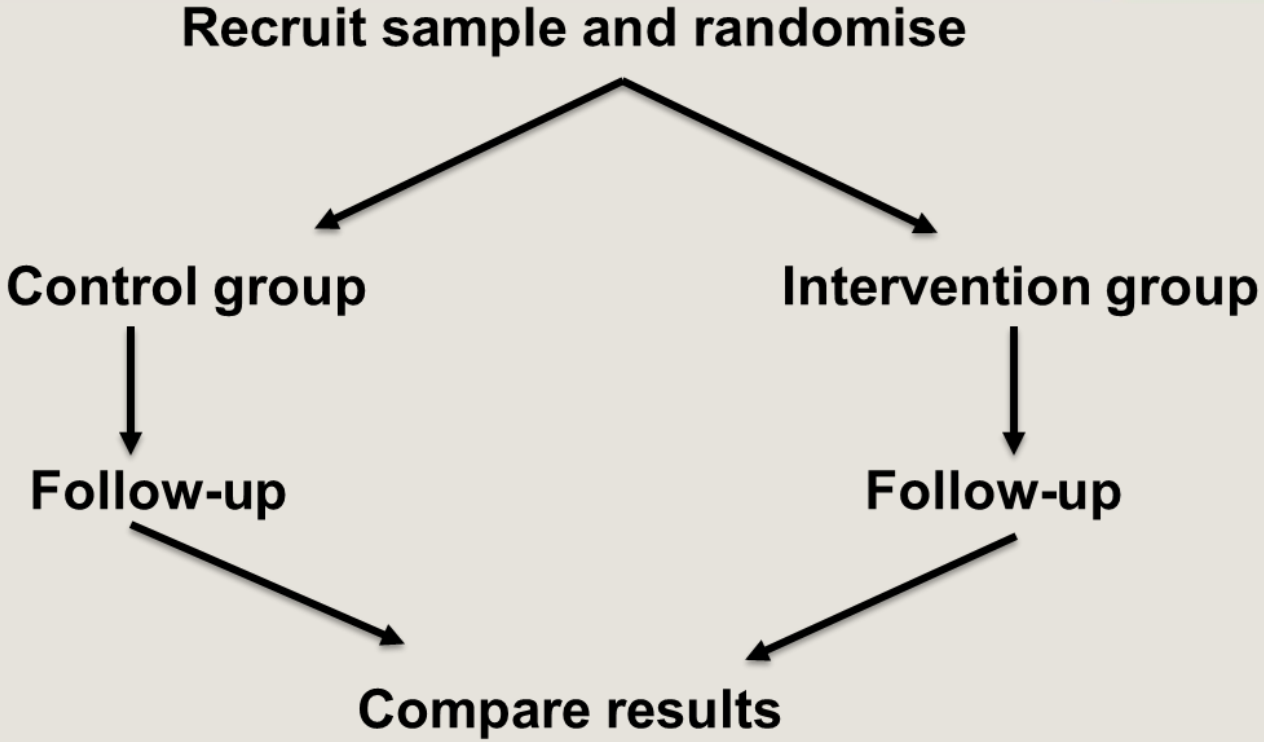


Skivington et al, 2021

Randomised controlled trials

- Evaluates the outcomes or effect of an intervention:
  - Does intervention A work?
  - Does intervention A work better than intervention B / usual care?
- Key strength of design is randomisation of participants to intervention and control groups
  - Minimises selection bias - allocation to groups is not determined by investigators, practitioners or participants
  - Produces comparable groups (e.g. age, gender, ethnicity, socio-economic status or other known / unknown confounders)

Randomised controlled trials



Feasibility trial

- Small-scale investigation to see if a larger trial would be possible
- Assesses practicality of trial procedures - e.g.
  - Participant recruitment and retention rates
  - Site and practitioner recruitment
  - Logistics of intervention delivery in different contexts
  - Adherence to intervention or protocols
  - Ease of data collection methods
  - Acceptability of outcome measures
- Stop / go criteria for progression to full trial
- Improves study design and reassures funders

Feasibility trial- CARERS Trial

- Assesses feasibility of a skills-enhancing group programme for carers of people presenting with complex emotional needs and chronic emotion dysregulation
- Family Connections has not been evaluated in National Health Service in the UK
- Feasibility trial is testing:
  - Recruitment of carer-service user dyads
  - Acceptability of intervention – how many complete it? What do carers make of it?
  - Acceptability of evaluation – how many are followed up? How many complete outcome measures?
  - Adverse events vs potential benefits
  - Number of participants needed for full trial

CARERS
Carers All Require Emotional support, Resilience and Skills

Definitive trial

- Scaled-up version of feasibility trial powered to detect a meaningful effect for the intervention (which is the only difference between the intervention and control group)
- Trial is delivered according to a protocol across multiple sites with close attention to trial procedures (both intervention and research)
- Researchers are often blinded to group allocation
- Involves a large team, takes long time and can be expensive
- Provides high-quality data that can inform decision-making
- RCT evidence is understood by health colleagues

Definitive trial- Community Navigators

- Community Navigators support people to identify and engage with community groups and activities. Based within NHS community mental health teams, but have local knowledge and expertise
- Trial evaluates their effectiveness in reducing loneliness of people with ‘treatment resistant depression’ (along with a range of other social outcomes)
- 313 participants recruited across six sites, randomised to intervention and control (care as usual) groups, now in final stages of follow-up
- Cost effectiveness and qualitative evaluations are embedded within the trial

Randomised controlled trial ethics

Is it ethical to randomise people so that some do not receive an intervention?

❌ If there is already strong evidence that the intervention is effective

❌ If the intervention is already being provided as part of routine care

✓ If there is some evidence that the intervention may help (e.g. from an uncontrolled pilot study) but there is genuine uncertainty about whether or not it is beneficial - principle of equipoise

✓ The benefits of the intervention are likely to outweigh the potential harms

✓ There is some evidence of its effectiveness in a different context

Randomised controlled trial ethics

- Informed consent - participants must fully understand the trial's purpose and procedures
- Participation must be voluntary, with no coercion
- Fair and equitable selection of participants is important so that all those who could potentially benefit have the opportunity to participate
- Control group should be provided with a realistic alternative or the usual care available to them
- Randomisation should be conducted independently of those collecting data
- Blinding should be used wherever possible to maintain integrity of the trial

Acknowledgement & Declaration of Interests

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Trial Methods: Recruitment, Data Collection and Retention

Community Navigator Trial

A novel **social connections intervention**

Aims to **reduce loneliness and thus reduce depression** for people with treatment resistant depression (TRD)

Trial Home page

Methodology

1:1
Randomised controlled trial

Multi-site project:
6 hospitals - secondary CMHTs

Referred by clinicians or trust researchers

Screened for eligibility

313
Patient-participants recruited

Data Collection:
Structured interviews with a blinded researcher

Protocol paper
Stefanidou et al. 2023

Recruitment

Prior to Recruitment

- **Engagement**: Promote the study, run Q&A sessions, and build relationships with clinicians/referrers (bearing in mind staff turnover).
- **Logistics**: Familiarise yourself with local systems (e.g. room booking, data storage, patient record software).
- **Materials**: Prepare posters, flyers, referral forms and scripts; ensure these are easily accessible (e.g. copies left in offices).
- **Expectations**: Recognise that not all referrals will result in eligible or willing participants.

Recruitment

During Long-term Recruitment

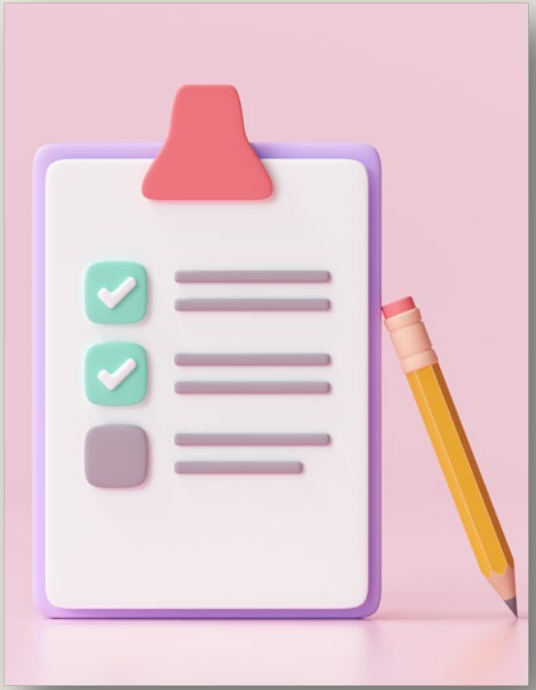
- **Ongoing engagement**: Maintain study visibility through regular team visits and updates.
- **Clinician relationships**: Prioritise 1-to-1 discussions with key clinicians about their caseloads.
- **Simple processes**: Make referrals straightforward (e.g. assist with completing forms).
- **Regular communication**: Send monthly newsletters with reminders, recruitment progress, and milestones (clinicians value seeing impact).
- **Recognition**: Show appreciation appropriately (thank you emails, certificates, or small tokens such as chocolates).
- **Motivation**: Introduce friendly competitions with small prizes for referrals.
- **Consistency**: Stay present and persistent - recognising how busy clinical teams are.

Recruitment

Initial Engagement with Potential Participants

- **Co-production**: Highlight that the study is co-designed with people with lived experience.
- **First impressions**: Build trust through clear, open conversations.
- **Transparency**: Explain inclusion and exclusion criteria clearly.
- **Choice**: Acknowledge that referred participants may decline to take part.
- **Empathy**: Use active listening; allow time for decisions, particularly if participants are feeling low or anxious.
- **Reassurance**: Emphasise that they can return later if not ready initially.
- **No pressure**: Be careful to avoid undue pressure (may reduce drop-out later).
- **Consistency**: Provide warm, ongoing communication (important if participants forget to follow-up).

Data Collection



Data Collection Design

- **Timeline**: Longitudinal trial over 14 months.
  - Main researcher-led data collection at **baseline, 8 months, and 14 months**.
  - Short online surveys at **4 months and 11 months** to maintain engagement.
- **Contact information**: Collect phone, email, and postal addresses (for letters).
- **Back-up contacts**: Gather additional details at consent (e.g. next of kin or clinician contact) to support follow-up if participants become uncontactable.

Data Collection

Data Collection Methods

- **Organisation:** Recruiting and completing follow-ups around the same time can be tricky - be organised (e.g. keep questionnaires printed in advance).
- **Flexibility:** Offer multiple options for data collection:
  - **Home visit** (if no risk)
  - **Meet on site** (hospital site, university)
  - **Meet in social settings** (e.g. library)
  - **Online** (MS Teams)
  - **Phone**
- **Surveys can be useful:** Participants may want to complete surveys in their own time (keep an online version ready).
- **Record keeping:** Keep and update logs of unblinding, withdrawals, any issues, or preferences at baseline and later follow-ups.

Data Collection

Data Collection Process

- **Practice:** Conduct practice sessions with colleagues before collecting data with participants.
- **If unblinded:** Explain carefully to participants and arrange follow-up with another researcher as soon as reasonably possible.
- **Timing:** Allow enough time for appointments so neither you nor the participant is rushed.
- **Pace:** Go at participant's pace - some participants prefer sessions split over multiple visits.
- **Flag risks:** Any risk should be addressed sensitively, ensuring participants feel supported.

Retention

Follow-up Outcome

- **Recruitment and retention:** One site recruited 105 participants (n= 313 overall trial). Retention at 8 months: 94% (86% overall trial); at 14 months follow-up: >91% (84% overall trial) to date.
- **Flexible timing:** +3 months window for follow-up appointments.
- **Participant choice:** Option to complete only the main outcome measure (less than 5 minutes) if they do not wish to complete the full data collection.
- **Consistency:** Having the same researcher collect data may help build **trust and rapport**, making participants feel valued and more willing to stay engaged.

Retention

Retention Strategies

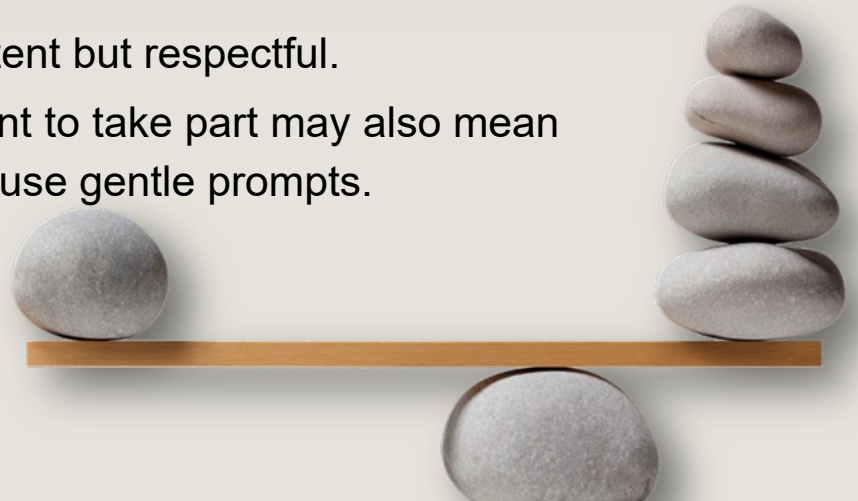
- **Be sensitive and approachable:** Using people skills helps maintain engagement.
- **Timing of contact:** Approach participants around 10 days before their follow-up is due and avoid booking before their due date.
- **Reminders:** Send a text before calling to state the purpose of the call, the time you will call, a reminder about blinding, and the incentive for taking part.
- **Preserve blinding:** Remind participants during the call to maintain trial integrity.
- **Incentives:** A £20 voucher for each data collection is reasonable and may have contributed to retention.

Retention Strategies

Balancing Persistence with Sensitivity

- **Try different modes of contact if one fails**: calls, text, WhatsApp, emails, online survey; contact clinicians if still within the team, or next of kin if necessary.
- **Perseverance without pestering:** Be persistent but respectful.
- **Respect participant choice:** If they don't want to take part may also mean they wish to skip a particular data collection - use gentle prompts.

- **Team discussion:** Discuss challenges and ideas in weekly team meetings to plan how issues can be approached.



Reflections

Your wellbeing matters in mental health research

The trial's journey: Trials are roller coasters full of challenges, thrills and moments of fun

Ongoing learning: Continue to train and review practices, what's working, what can be improved and think proactively

Stay connected: Visit us and explore our research blogs 🌞

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Using Lived Experience to inform trial methods & procedures

Lived Experience in RCTs

- What is Lived Experience (LE) in research?
- Why is LE important?
- How to utilise LE?
- Tools to monitor & evaluate LE

- **Case Study:** The CARERS Trial
  - How has LE been utilised?
  - Key Insights from LE?
  - Learning from Feasibility Trial

Putting People First

What is LE in Research?

The unique knowledge & understanding gained from having personally experienced a particular condition, situation, or social context

i.e. mental health issue, homelessness, or health inequality

Also known as

Patient & Public Involvement & Engagement (PPIE)

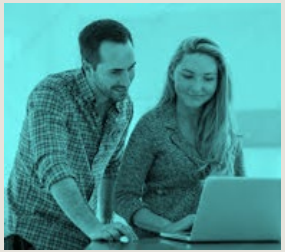
Why is LE Important?

Involving people with first - hand knowledge - *"lived experience experts"* – enhances research by providing authentic, relevant insights that traditional methods may miss, leading to more user-informed & effective research & policy development.

How to Effectively Utilise LE

Researchers should involve people with LE as equal partners throughout the research process, from defining the problem to disseminating findings.

This requires creating safe, accessible, & trusting environments & providing adequate training & support for participants / staff.



Tools to Monitor & Evaluate LE

Methods

- Co-production/design
- Participatory methods
- Creative/visual methods
- LE reference groups

Resources

- User-Led Organisations
- Foundations/charities
- Academic/Prof bodi es

Evaluation Tools

- 4Pi Standards
- PiiAF
- PIRIT
- The Cube
- GRIPP2
- PPEET

The CARERS Feasibility Trial

CASE STUDY

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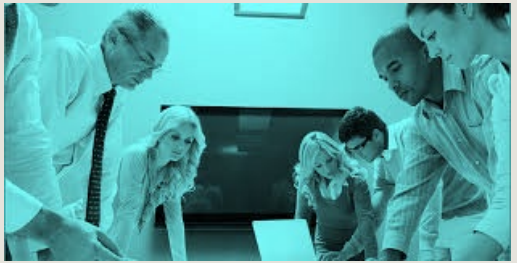
Use of LE in CARERS Trial

- Unusual in having PWLE* initiate the trial
- Co-Chief Investigator as PWLE
- Focus Group of PWLE
- Formed Advisory Group – set up pre-trial funding
- Carers & Service Users – adaptations for regularly meeting
- Theory of Change workshop
- Maintaining active interest
- Reviewing research findings
- Dissemination



*Person with Lived Experience

Key Insights from CARERS Trial

From CARERS

- Prepared to WAIT
- Receive no support
- Normalising in group
- Key life skills
- Gratitude

From Service Users

- Want help for carers
- Keep informed
- Maintaining involvement
- Benefit from carer's skills acquisition
- Gratitude

For Research

- Identifying Academics
- Funding study
- Selection of study sites
- Understanding of NHS
- Identifying PPIE members
- Intervention knowledge
- Training provision
- Troubleshooting
- Appropriate terminology
- Passion
- Perseverance

Learning from Feasibility Trial

- PWLE have to break down many barriers to initiate/lead research
- Recognising power imbalances
- Overwhelming support from Carers in advisory group
- Difficulties maintaining Service User involvement
- Veracity of survey tools i.e. measuring relationship improvement
- Monitoring PPIE activities
- Evaluating PPIE activities

LE- Essential for Improving Research

- *"We cannot continue to do research about patients without patients.*
  The time for tokenistic involvement has passed"

  - Dame Sally Davies, Former UK Chief Medical Officer

- *"When we engage patients meaningfully, we don't just get better research results - we get research that actually matters“*

  - European Patient’s Academy 2025

- *"The insights patients bring to research design can prevent years of pursuing the wrong questions with the wrong methods"*

  - Dr. Richard Smith, Former Editor, BMJ

Trial Management and Site Liaison: Spinning plates and juggling balls

"Well designed trials are the basis for addressing important clinical questions, but science alone will not be sufficient to successfully deliver a trial"

(Farrell et al, 2010)

- ✓ Effective trial management is linked to successful trial delivery
- ✓ Influences processes (procedures, regulatory oversight) but also outcomes (recruitment, retention)
- ✓ Limited available guidance, especially for social trials

Management versus Oversight

Chief Investigator

- Responsible for research design and development (and securing funding!)
- Expertise in the field
- Overall responsibility for the trial
- Generally distant from day-to-day management

Trial Manager

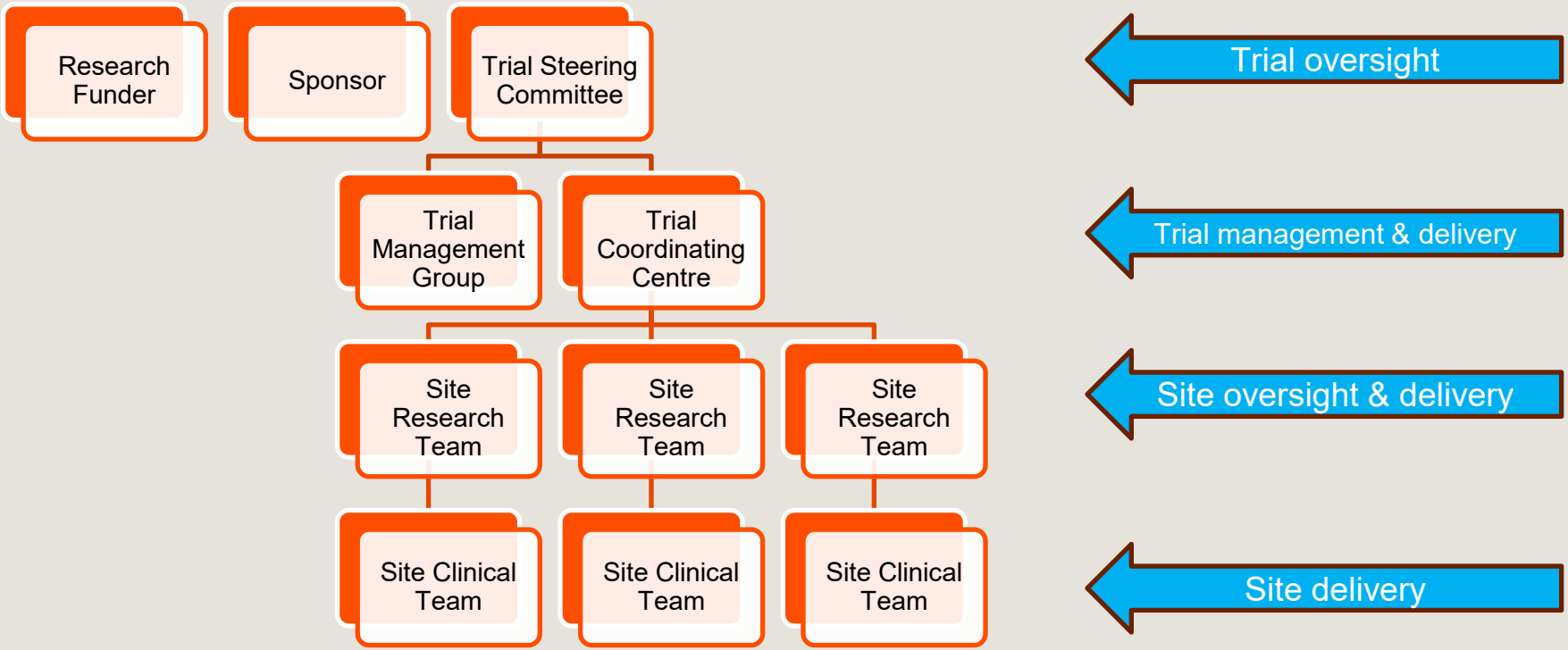
- Often not involved in research design
- Coordinates and is responsible for day-to-day management
- Knowledge of the field
- Multi-skilled – organisational, administrative, management and research capabilities

Competency Framework for Trial Managers

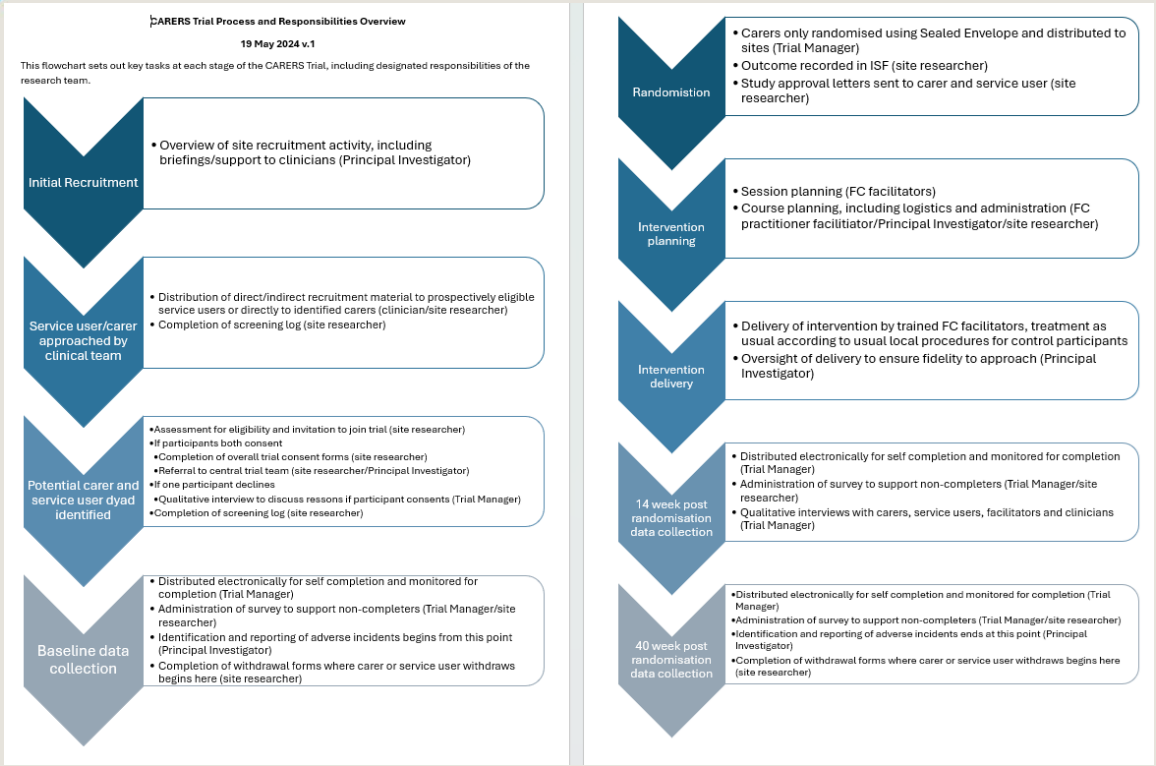
- Communication and interpersonal skills
- Adaptability and flexibility
- Team working
- Planning and organising
- Citizenship
- Continuous improvement
- Problem solving and decision making
- Leadership and management
- Creative and analytical thinking
- Influencing and negotiating
- Strategic thinking

(UK Trial Managers Network, 2023)

Managing a complex (enough) structure: The CARERS Trial



The criticality of coordination



Recruitment
Trial coordination centre
Site research teams
Site clinical teams
Data collection
Trial coordination centre
Site research teams
Intervention delivery
Trial coordination centre
Site research teams
Site delivery teams
Participant engagement and retention
Trial coordination centre
Site research teams

Managing the flow of information and expectations

Reporting upstream

- ✓ Personalised information and briefings
- ✓ Progress reports
- ✓ Adverse incidents

Guiding downstream

- ✓ Personalised information and briefings
- ✓ Protocols and processes
- ✓ Standardised forms and templates

Participant engagement

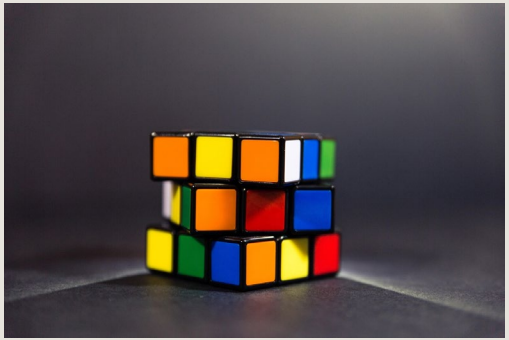
- ✓ Updates and outreach

Roadblocks, barriers and challenges

- ✓ Differing priorities between research settings and practice settings
- ✓ Being one trial among many
- ✓ Lack of trial familiarity (or lack of social trial familiarity) in research sites requiring support
- ✓ Practitioner ‘buy in’ and resources for trial involvement
- ✓ The time needed for research governance and regulation

Stepping into health spaces… and navigating GCP

- ✓ Arbitrary, socially constructed distinction between health and social care, and social trials may enter health spaces
- ✓ Clinical trials in health spaces (for medication or medical devices) and subject to Good Clinical Practice (GCP) regulations
- ✓ High levels of standardisation – this can be a strength, but does not always translate for social interventions
- ✓ Research partners used to working with GCP may be reluctant to step away from this, even where it is not appropriate. Good knowledge of GCP is critical



Strategies for effective trial management

- ✓ Write trial protocols with a view to how they will be implemented
- ✓ Build relationships with key site research staff and sustain key lines of communication, including formal and informal check -ins – be approachable
- ✓ Develop standardised documentation, clear processes and information packs – and assume you will need to remind site staff about these regularly
- ✓ Identify designated update points with sites
- ✓ Maintain regular communication with participants, especially control group participants

Outcomes for the CARERS Trial

Recruitment

✓ 49 carer and service user dyads recruited, all sites achieving local targets within six months

✓ 48 dyads completed baseline data collection

Retention

✓ 67% of intervention group participants completed the intervention, with feedback on why others struggled to engage, enabling future mitigation

✓ 90% of participants completed follow up data collection at 14 weeks

Acceptability

✓ Feedback from participants indicates trial processes as acceptable and ongoing trial contact as welcome

CARERS
Carers All Require Emotional support, Resilience and Skills

Thank you!

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