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Returning to work after trauma

The ROWTATE research programme: Challenges, Progress and Acceptability

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ROW TATE
RETURN TO WORK AFTER TRAUMA

Summary

- Introduction to the ROWTATE research programme
- Research challenges and solutions
- Progress:
  - Intervention development
  - Feasibility study
  - Main trial
- Preliminary findings on acceptability from the main trial

Introduction – ROWTATE Study

7 year programme of research: March 2019 – December 2025

Aim:
To develop, evaluate and assess implementation of a vocational rehabilitation intervention to enhance return-to-work and improve quality of life and wellbeing in people with at least moderate trauma (ISS ≥ 9)

8 MTCs across UK; Nottingham lead site

Multidisciplinary team of clinicians and academics

Overview of ROWTATE Research Programme

Extensive PPI informing all work packages

Work Package 1
Intervention development

Develop intervention, training package, outcome measures and data collection tools

Months 1-12

Work Package 2
Feasibility study

Test feasibility of recruitment, intervention delivery, fidelity, acceptability

Months 13-32

Work Package 3
Main trial

Test effectiveness and cost effectiveness of intervention

Months 32-82

Work Package 4
Process evaluation and implementation study
Assess acceptability, fidelity, practical & implementation issues, develops implementation resources

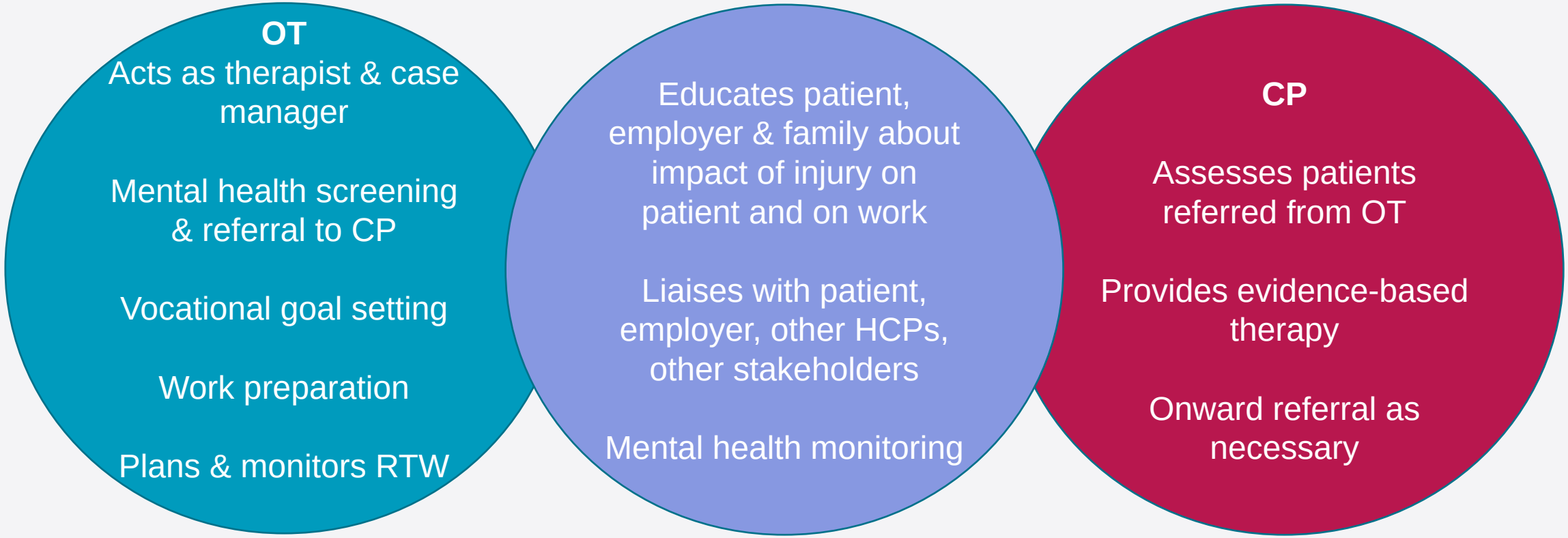
ROWTATE Intervention

Vocational rehabilitation (VR) aims to support people to return to or remain in work

- Delivered by occupational therapists (OTs) and where needed, by clinical psychologists (CPs)
- Starts early ≤12 weeks of injury
- Individually tailored; lasts ≤12 months
- Delivered predominantly remotely (video-call/phone)
- OTs and CPs receive VR-training and monthly mentoring

ROWTATE intervention

Joint working between OT and CP



Challenges and solutions

Before study starts

Challenges

- Recruiting large sites
- Some inexperienced PIs
- Produce protocol and study documents – multiple work packages = multiple protocols/documents
- Approval from sponsor
- Multiple REC submissions

Solutions

- Larger sites compensate for smaller sites
- CI support for PIs & staff
- RCF funding for protocol/document development pre-programme start

- Sponsor-specific requirements, good working relationship
- Same REC for all submissions

Set up phase

Challenges

- Excess treatment costs:
  - ETC process changed x2: CCGs → NHS Trusts
  - CRN confusion - NHSE commissioning
  - Trusts reimbursed once “threshold” is reached - some never reached threshold
  - ETC process varied across Trusts
  - Started early - negotiations took 1 year
- Delays in R&I approvals at sites (C&C, contract signing, LoA):
  - Covid pause; backlog
  - Unclear processes & staff shortages/turnover
  - 1 year to open 8 sites

Solutions

- Started early
- Lead site reimburses each site for ETCs
- Worked with:
  - CRN to agree payment model
  - Lead site to agree payment schedules/contracts
- Constant chasing of R&I depts., escalating issues, informed NIHR

Running of the study

Challenges

- Insufficient OTs/CPs to deliver intervention
  - Major challenge to patient recruitment
  - NHS staff shortages/redeployment/trial therapist turnover
- Researcher capacity:
  - Single researcher sites
  - Staff turnover, post-Covid recruitment difficulties, approval processes
- PI turnover

Solutions

- Intervention-only sites
- Private OTs/CPs – 11 steps in HR and contracting process; Bank OTs (NHSP or site)
- Floating OTs/CPs deliver intervention across multiple sites –R&I & IT governance issues
- Trained 70 OT/CPs (estimated 24)
- Some researchers approved to recruit across multiple sites
- Recruited new PI

Data Collection – patients & therapists

Challenges

- Ensuring high return rates for patient questionnaires - 3, 6, and 12 months (primary endpoint)

- Multiple outcome measures:
  - Which are most important?
  - Long questionnaires

- Intervention data - difficulty getting complete data from therapists

Solutions

- Priming texts/calls, vouchers (unconditional)
- Shortened questionnaires
- Phone/electronic/paper collection methods
- Phone follow-up of non-responders

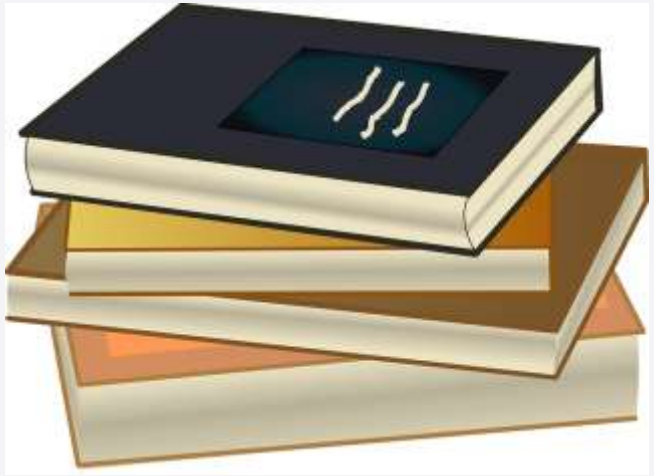
- PPI helped choose outcome measures, shorten questionnaires and FU strategies

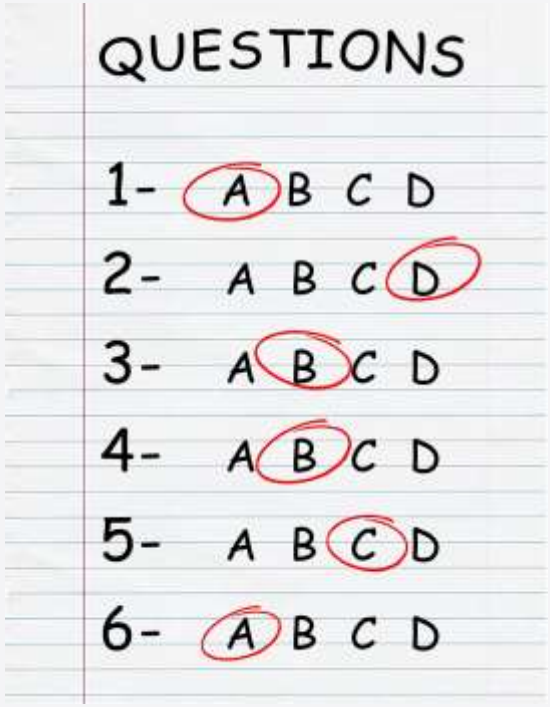
- Flagging missing data in database, reminders
- Exploring reasons in mentoring and a lot of chasing

Progress of the ROWTATE research programme

Achievements – intervention development

- Face-face intervention
- Intervention manual
- Therapist training and mentoring package
- Patient questionnaires





A really big challenge!

Achievements – feasibility study plans: major changes

Pre-Covid Plan

Non-randomised study, 40 patients, 2 MTCs, 3 months follow-up

Case studies: 10 patients & linked OTs/CPs /employers/commissioners

Focus groups & interviews trauma patients

Both Pre and Post-Covid Plan

Assess OT/CP competency & evaluate training

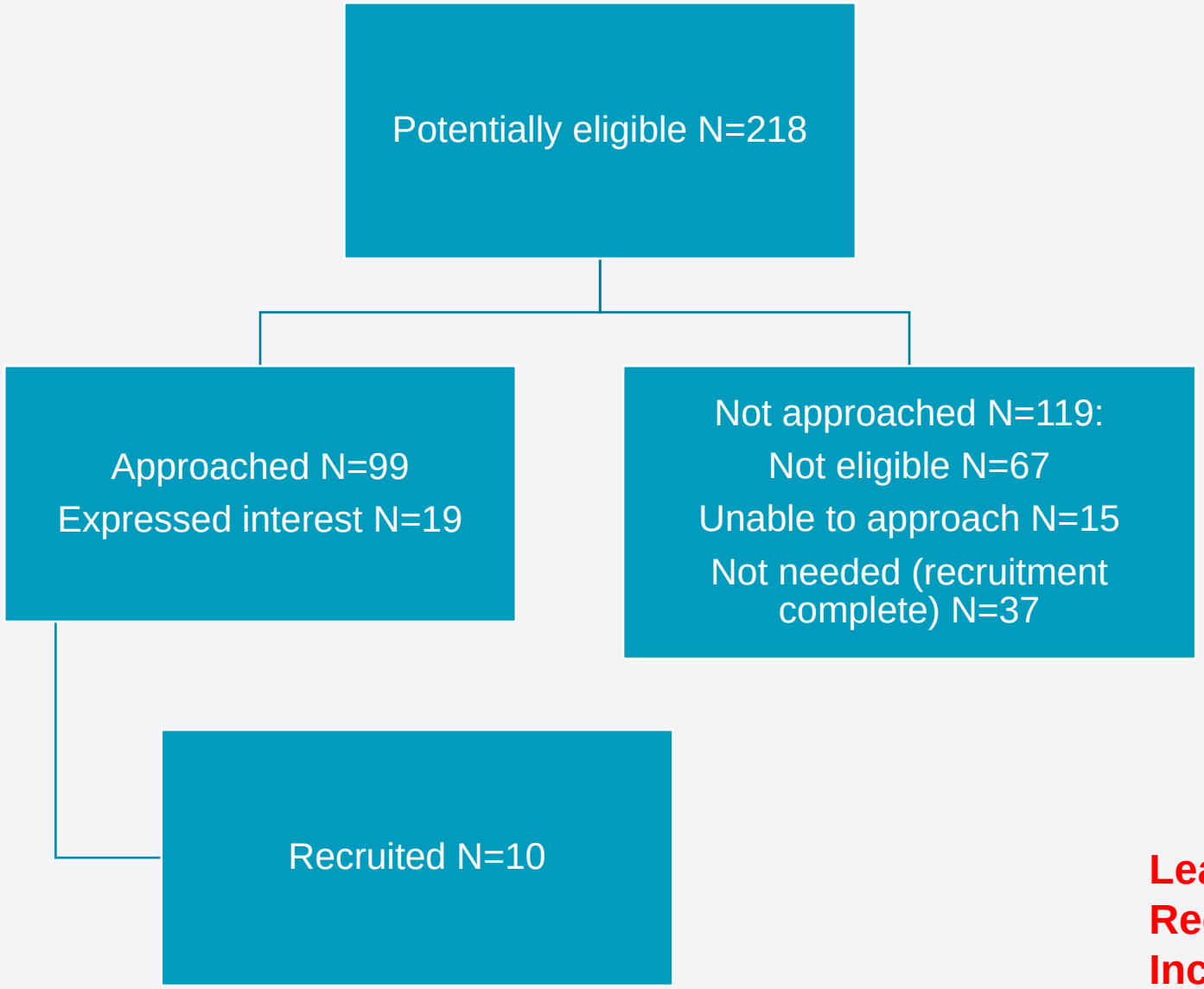
Assess fidelity

Post-Covid Plan

Adapt for remote intervention
Review literature
Survey & interviews with OTs/CPs: use of, factors influencing and options for remote delivery

Train OT/CPs remotely
Recruit 10 patients & deliver intervention remotely
Interview patients/OTs/CPs /employers

Feasibility study recruitment (Oct 20–Jan 21)



- Mean age = 42
- 60% male
- 40% from black/ethnic minority group
- Median years education = 18
- 40% paid employment, 20% self-employed, 10% full time education, 30% multiple jobs/education
- 70% RTAs
- Median ISS = 11
- Median LOS = 6.5 days
- Mean days injury-recruitment = 58

Learning for main trial:
Recruitment rate only ~ 5%
Increased number of study sites from 5 to 8

Feasibility study findings

Intervention delivery

(n=10 patients)

- 90% started ≤12 weeks post-injury
- 13 OT sessions/pt; 98.5% remote
- 7 referred to CP; 3 sessions/pt; 3 had only 1 session, 100% remote
- 35 weeks on OT caseload and 8 weeks on CP caseload
- No withdrawals

Fidelity

- **High percentage of intervention components** were delivered as planned (85% for OTs and 93% for CPs).

Learning for main trial:
More patients referred to CP than expected
Some needed little intervention
Instituted one month of "watchful waiting" by OT for those with milder symptoms

Feasibility study findings - acceptability

OTs/CPs (n=6)

- Remote intervention acceptable; some patients may need some F2F contact
- Bult good rapport with patients, but took longer
- Time:
  - Reduced travel time = more time for rehab
  - Getting used to technology takes time
- Good fit with:
  - “new” way of working (Covid)
  - service therapists felt they should be providing
- Better/more effective VR than usually provided
- Increased confidence to deliver remotely
- Difficulty engaging employers

Patients (n=4)

- Remote intervention acceptable; preferred by some – reduced travel, convenience, flexibility, comfort of home
- Therapist understood their needs and helped pt work towards goals
- Understood need for VR, felt it was beneficial & changed how they managed RTW
- Good relationship with therapist

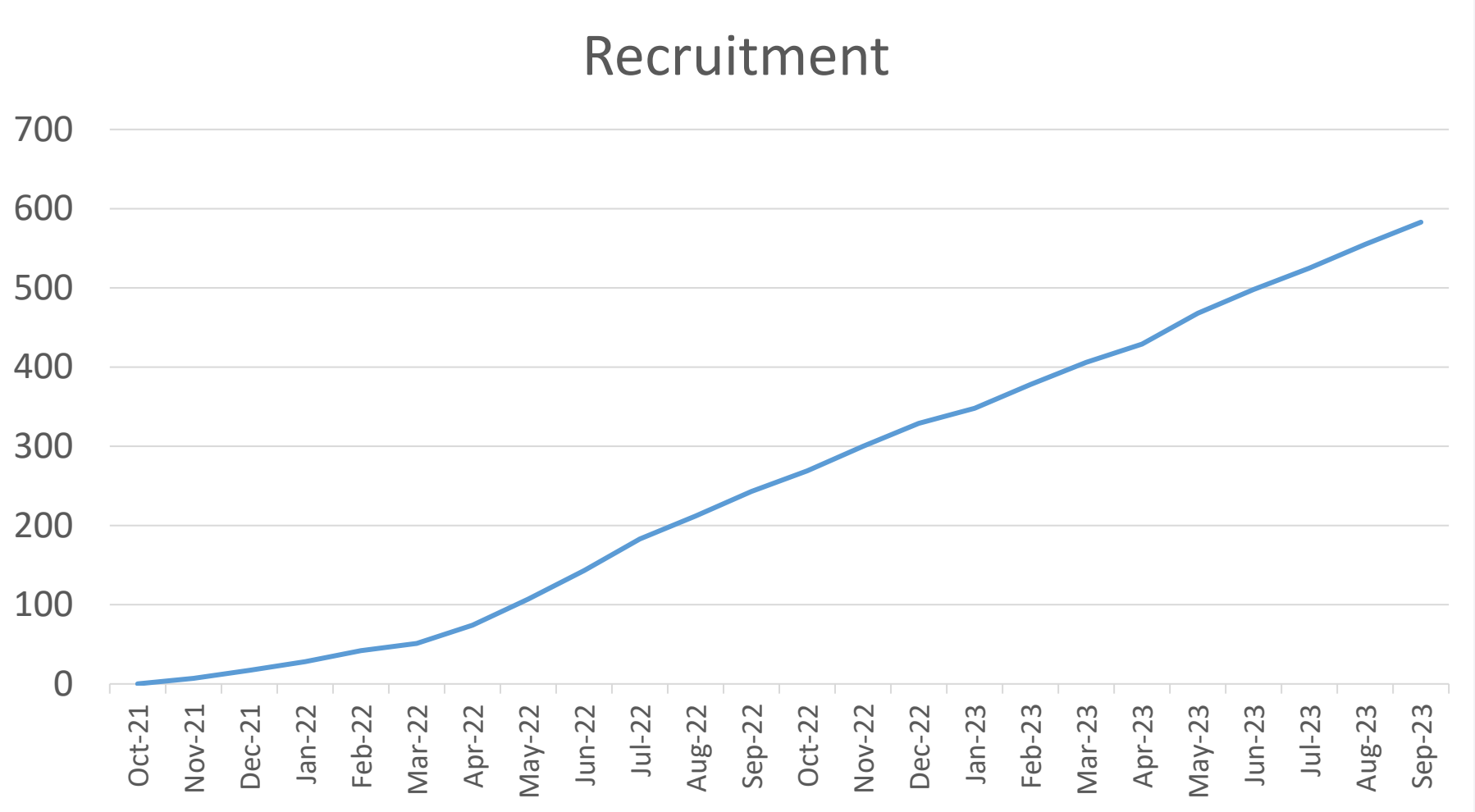
Learning for main trial:
Predominantly remote delivery, F2F if needed
Training/mentoring to address employer engagement
Employer network to provide advice to research programme

Achievements to date – main trial

Screened >11,000 patients

Approach ~28% of screened patients:
- 52% face-face
- 22% phone
- 26% post

Consent 18% of approached:
- 78% face-face
- 21% phone
- 1% post



Recruitment rate ~5%

Achievements to date – main trial

- ✓Trained 70 therapists – hybrid & remote only
- ✓Post training:
  - ✓All judged competent to deliver intervention
  - ✓High levels of confidence to deliver the intervention

- ✓288 patients randomised to receive the intervention

- ✓Follow-up data (return to work) obtained from:
  - ✓88% at 3 months, 80% at 6 months, 82% at 12 months

Achievements to date – process & implementation study

- ✓ Interviews:
  - ✓Acceptability of the intervention (6 participants, 13 therapists)
  - ✓Implementation issues (10 therapists, 1 commissioner, yet to start employers, GPs, participants, carers)

✓Fidelity assessment and analysis of mentoring records underway

Acceptability to patients

Excellent, invaluable, necessary…I can't think of enough positive words

To be honest it didn't take too much effort on my part because my OT was so approachable and relaxed and it was the way that she communicated and everything was done via telephone or Teams, so there was no need to travel, it was always whenever I was available

I think I had the same goals and ambitions as what they had really, for me to get back to full health and back fit again

having that support and someone encouraging you and signposting you gives you the confidence to be able to tackle things as well…doing the questionnaires around mood and anxiety did definitely help me to get access to what I needed to start recovering

If I hadn't participated in this study I would've gone back to work for a short period of time and I would've either resigned because I wouldn't have been able to do the job, or I would've been performance managed out

I would say I felt confident…I think I probably wouldn't have had the initiative or known how to look for some of it [support] otherwise

Acceptability to therapists

I think it's a really rewarding job, doing the ROWTATE stuff, because you get those good outcomes of getting people back to work

The time it took to constantly be calling them or setting aside time to arrange an assessment and them not being available. Or setting aside time to do the assessment and being interrupted by someone else on the hospital ward. Or just not contacting me …That was just very time consuming

I've really enjoyed it. It's been a lovely opportunity to be able to see people from the acute through to the community, to have that year follow-up and to see what a difference can be made by having someone who is there throughout

participants have said things like, "You hold all of me," …as in you're the one person I talk to about everything. I talk to you about my physio, my emotional health, my return to work, my family and the impact on them. So, I'm the one person that seems to have all of that information

the [employer's] relationship with the employee has not been good… but when I did speak with them and meet them about his return to work, I think they were thankful that I managed to reassure them

I think I've really helped the participants who signed up. I think they've really appreciated it and it's opened their eyes to do things

Conclusions

- Many challenges, but on track to deliver full-scale trial
- Lots of experience of finding solutions
- Intervention appears to be acceptable to patients and therapists
- Learning a lot about factors which will affect implementation into NHS
- Lots of work still to do!

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Thank you!

Any questions?

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Participating Major Trauma Centres

Bristol: Southmead

Cambridge: Addenbrooke's

Leeds: Leeds General

London: Royal London & St Marys

Newcastle: Royal Victoria

Nottingham: Queen's Medical Centre

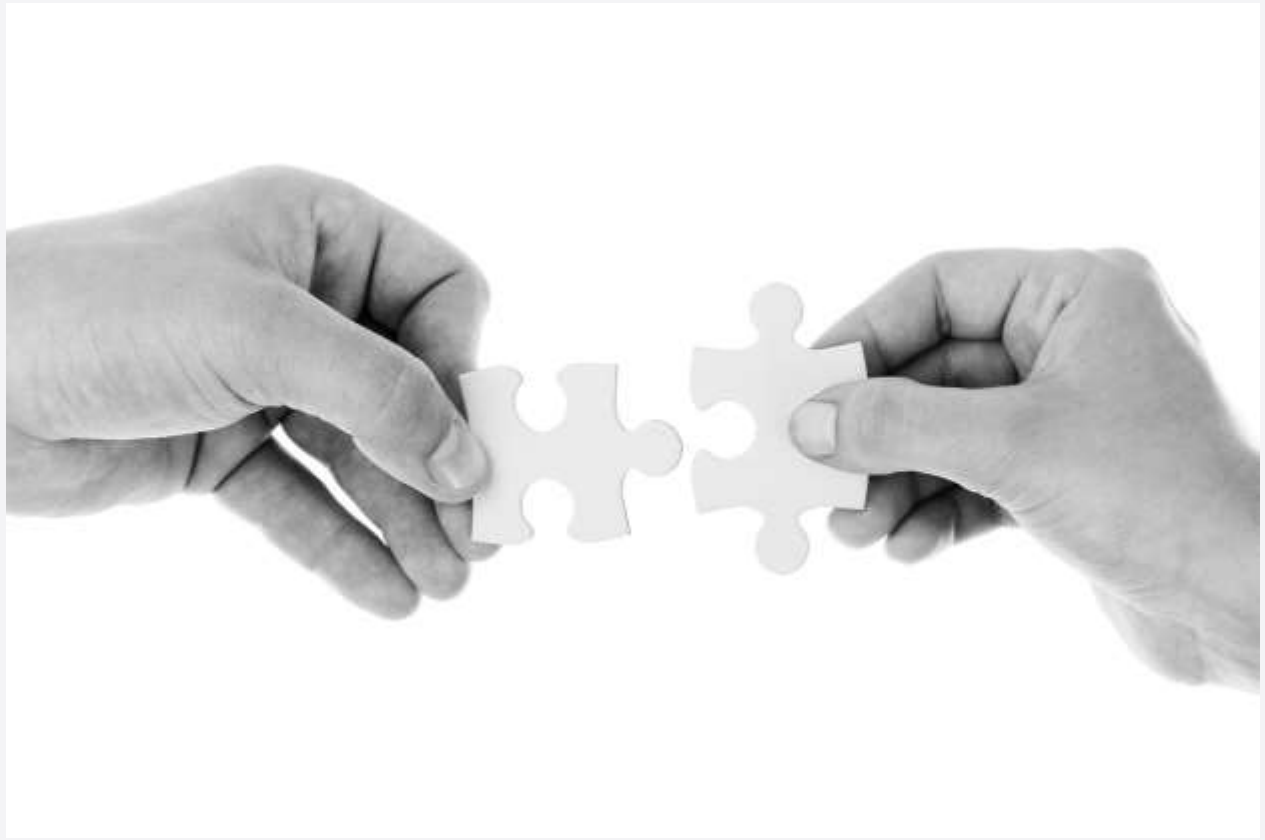
Southampton: Southampton General

Multidisciplinary team

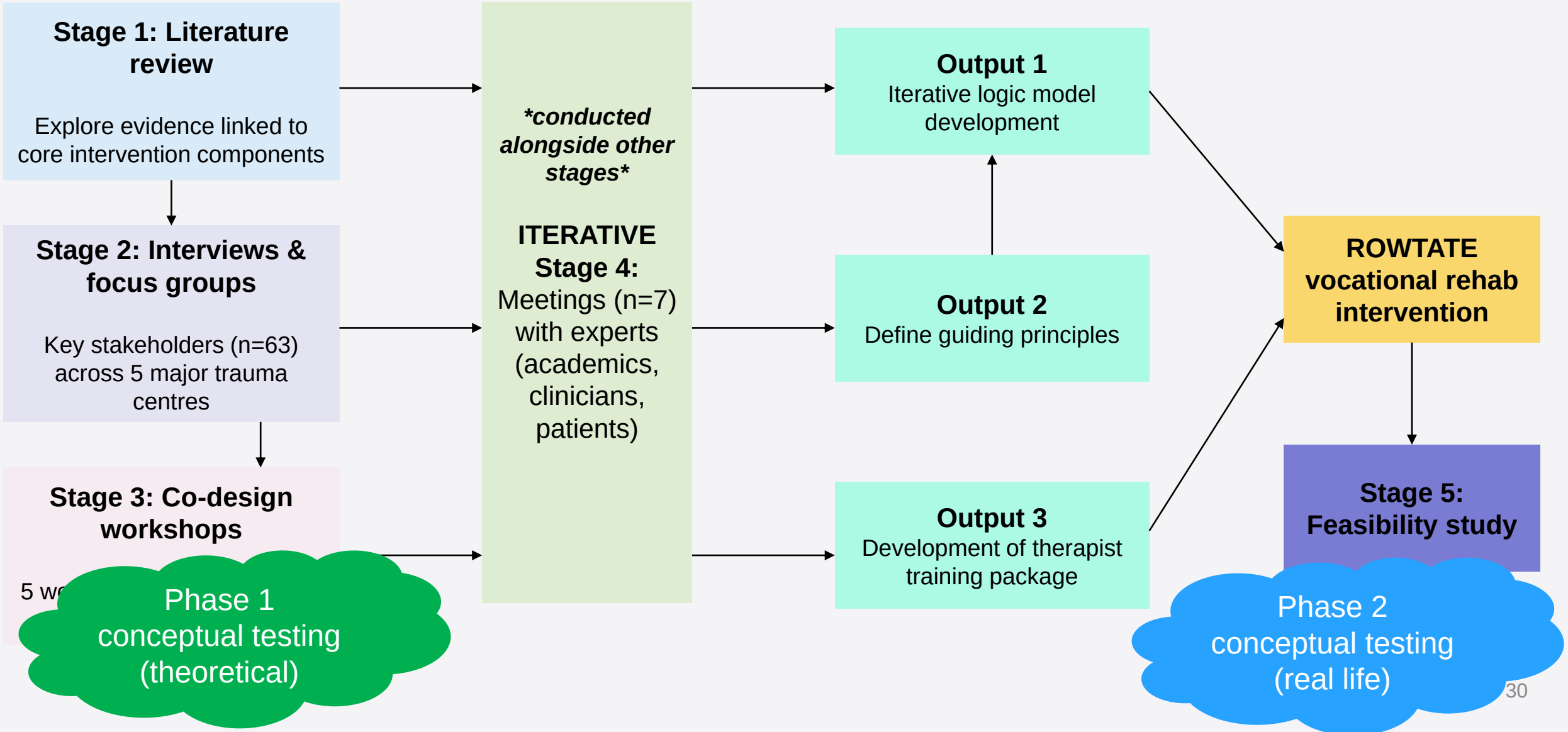
- Trauma surgeons
- ED clinicians (medics and nurses)
- Rehab consultants
- Occupational therapists
- Clinical psychologists
- Community psychiatrists
- General practitioners
- Clinical trials and complex intervention specialists
- Statisticians
- Health economists
- Implementation scientists
- Qualitative researchers

ROWTATE Intervention – A “complex” intervention

- MRC defines complex interventions as ‘*those with **several interacting components***’
- These usually depend on **behaviours** of those delivering and receiving the intervention, or a need to **tailor** the intervention to different contexts/settings
- Often influenced by the context in which they are implemented – complex environments and systems



Methods: Sequential PBA approach



Results: Key Guiding principles

Treatment focus is physical, not psychological.

Patients not asked about employment and plans to return to work in acute setting.

Quickly discharged injuries will miss support (e.g. stabbing, fracture).

Failure to understand each individual reaction/adaptation to traumatic injury is unique.

Vocational rehabilitation interventions need to assess individual goals at different points over time.

Health service gaps/waiting lists slow recovery (particularly psychological support).

Results: Key guiding principles

Communication and referral gaps between services mean transfer of care may be patchy.

Healthcare does not relate easily to third sector.

Legal rights/workplace policies unclear to patients.

Impact of less visible injuries may interfere with return to work if not recognised.

Disability and stigma may affect negotiation with employer/colleagues.

Employer size/budget constraints impact motivation to accommodate injured employee needs.

Intervention Mechanisms

Identifying people employed at **injury onset**.

Early identification of individuals requiring vocational rehabilitation.

Supporting return to work/exploring **work alternatives.**

Tailoring support to individual needs.

Ensuring **timely psychological support**.

Educating patients about the impact of injury and returning to work.

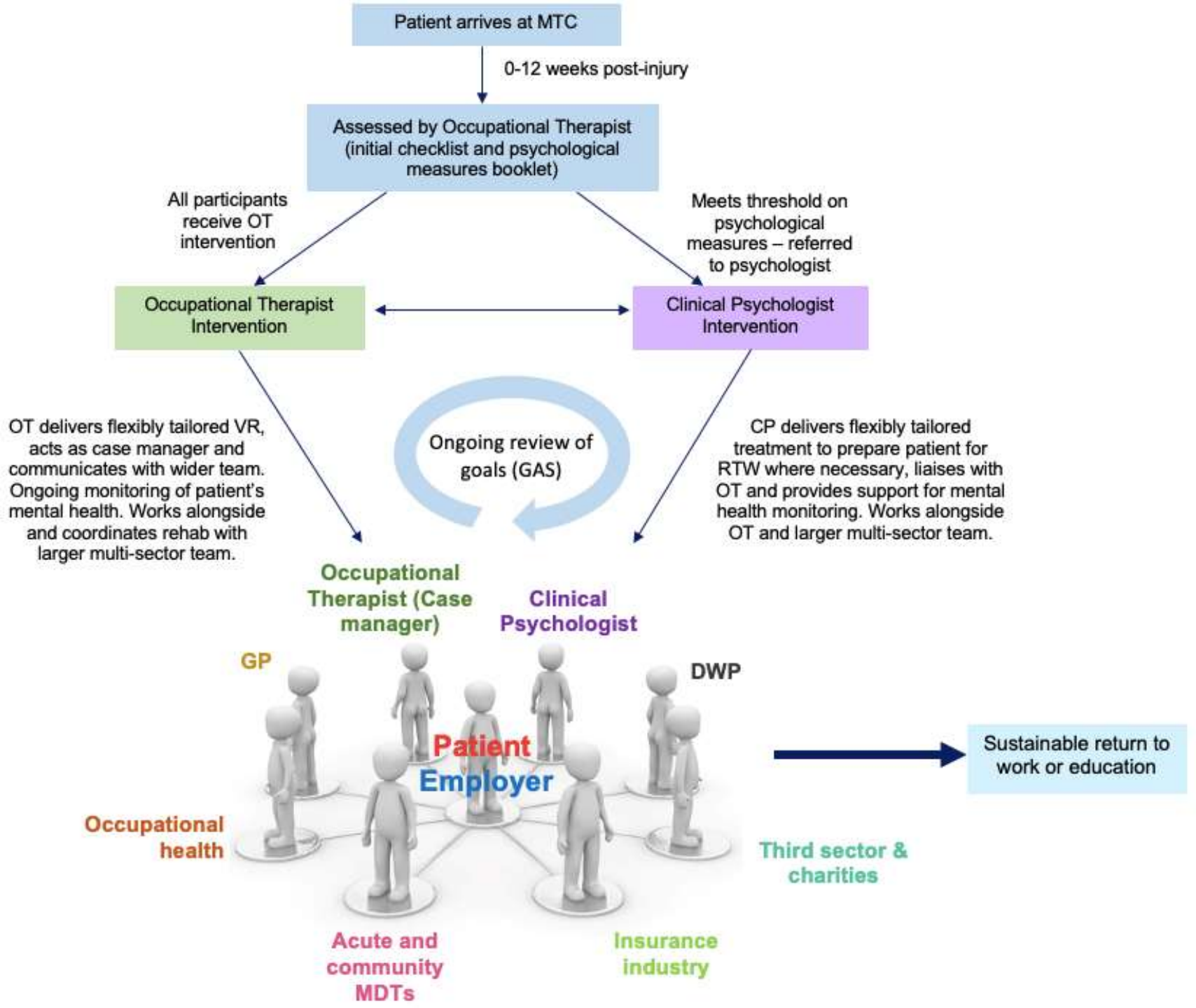
Educating and advising employers about the impact of injury on work and how to support a RTW.

Vocational **goal setting** and review.

Central point of contact for stakeholder communication.

Enabling inter-agency and **cross boundary** communication.

Making GP aware of vocational rehabilitation needs.


Patient arrives at MTC
0-12 weeks post-injury
Assessed by Occupational Therapist (initial checklist and psychological measures booklet)
All participants receive OT intervention
Meets threshold on psychological measures – referred to psychologist
Occupational Therapist Intervention
Clinical Psychologist Intervention
OT delivers flexibly tailored VR, acts as case manager and communicates with wider team. Ongoing monitoring of patient's mental health. Works alongside and coordinates rehab with larger multi-sector team.
Ongoing review of goals (GAS)
CP delivers flexibly tailored treatment to prepare patient for RTW where necessary, liaises with OT and provides support for mental health monitoring. Works alongside OT and larger multi-sector team.
Occupational Therapist (Case manager)
Clinical Psychologist
GP
DWP
Patient
Employer
Occupational health
Third sector & charities
Acute and community MDTs
Insurance industry
Sustainable return to work or education

Themes from the acceptability analysis (preliminary)

Attitude
How an individual feels about the intervention

Burden
Perceived amount of effort required to participate in the intervention

Ethicality
Extent to which intervention fits well with individual's value system

Intervention coherence
Extent to which participant understands intervention and how it works

Perceived effectiveness
Extent to which intervention is perceived as likely to work

Self-efficacy
Confidence to perform behaviour required to participate in intervention