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North Wales Organisation for
Randomised Trials in Health & Social Care
Sefydliad Hysbysu a Gofal Cymdeithasol Gogledd Cymru

PrAISED

Promoting Activity, Independence
and Stability in Early Dementia

Process and Realist Evaluation

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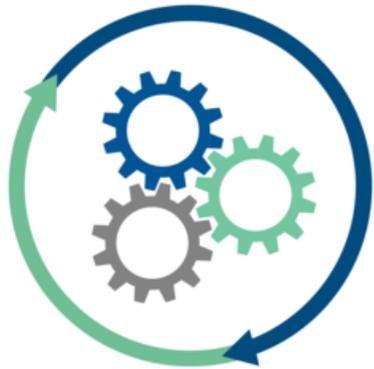
- ‘A study which aims to understand the functioning of an intervention, by examining intervention delivery, mechanisms of impact, and contextual factors’.
MRC guidance: <https://www.bmj.com/content/bmj/350/bmj.h1258.full.pdf>
- When evaluating complex interventions, such as PrAISED, process evaluations are essential complements to RCTs. Why?
- An RCT **identifies a link** between cause and effect (linear model). A process evaluation **explains the link** between cause and effect, by identifying mediating factors (mediated model) that generated intervention outcomes



- Mediating factors include: Mechanisms of impact (participant responses) and contextual factors (environment and cultural/social contexts)
- Example: Participant A and B in PrAISED obtained the same score on balance post-intervention.
- They might have had same results through different mechanisms. E.g., Participant A through enhanced care support, Participant B through self-motivation
- Why is this important to know? Implication is that successful implementation in real world practice requires care support strategies and/or motivational strategies

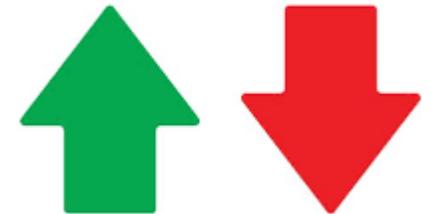


- The process evaluation was carried out alongside the RCT:
<https://www.sciencedirect.com/science/article/pii/S0378512218307874>



- Aims: to determine participants' reactions to the programme, and to explain findings from the RCT, by identifying facilitators and barriers to achieving positive outcomes
- Design: qualitative study
- Methods
 - Eighty-eight interviews with 44 participants with dementia, and 39 caregivers.
 - Sixty-nine interviews with 26 therapists.
 - Two time-points: baseline (6th month) and follow-up (12th month)
 - 15 videorecording of therapy sessions
 - Researcher notes

- Overall responses to PrAISED: (80%) participants reported a very positive experience with PrAISED
- **Facilitators** to achieving positive outcomes: Perceiving progress toward desired goals, positive expectations, therapists' skills and rapport with participants, and caregiver support
- **Barriers** to achieving positive outcomes: Cognitive impairment, chronic physical health problems and intercurrent acute illness and injury, 'tapering' (progressively infrequent supervision intended to help develop habits and independent activity), COVID-19 pandemic
- Published paper:
<https://www.medrxiv.org/content/10.1101/2022.12.20.22283555v1>





- ‘A study which aims to **understand what ‘worked’ in an intervention, ‘for whom’ and in ‘what contexts’**
- It recognises the individuality and diversity of participants’ experiences of an intervention
- Classic RE question: For what type of participant was the intervention most/least beneficial, why, and under what circumstances?
- It suggest ways to improve effectiveness and inform decisions about implementation in real world settings



- RE begins by identifying **Context-Mechanism-Outcome (CMO)** configurations.
- Context: **Environment** (e.g., places, people, time, institutions, social relationships, rules, norms, expectations and resources available) in which the intervention is delivered
- Mechanism: **Responses** (cognitive, emotional, motivational etc) by actors of the intervention (participants, caregivers and therapists) that generate intervention outcomes
- Outcome: Intended and unintended **consequences** of an intervention, resulting from the activation of different mechanisms in different contexts



- CMO statement: ‘In this context (**C**), that particular mechanism (**M**) fired for these actors, generating that outcome (**O**)’
- CMO statements are tested through the data and refined iteratively until a definitive version is ready



- Aims: to determine what contexts and mechanisms generated ‘**social inclusion**’ in PrAISED participants
- Why social inclusion? Results from the PE identified social inclusion as a core outcome in PrAISED
- Design: Mixed methods study based on secondary analysis of data from RCT and PE
- Methods



Development of CMOs: Analysis of 10% transcripts and video recordings of therapy from PE

Testing of CMOs: 22 dyadic interviews with participants and caregivers, and 39 interviews with therapists

Refinement of CMOs: RCT data (calendars, balance score), videos and researcher notes



CMO1: When the therapist was able to make therapy sessions tailored to participants' preferences and passions, they were engaging (C). The participants experienced sessions as "pleasant and fun" (M). This led to high levels of social interactions with the therapist (O).

CMO2: When therapy visits were not regular or tapered down (C), the participants reduced their engagement in the intervention losing physical fitness (M), which had negative impact on their willingness and ability to engage in social activities (O)



CMO3: Some participants perceived achievement of benefits through PrAISED, such as increased balance (C). This boosted their confidence and reduced caregiver risk-aversion/gatekeeping attitude (M). This in turn resulted in participant's increased participation in social activities (O)





Conclusion

- Process evaluation and realist evaluation are key companions to RCTs
- They are resource-intensive and require careful planning, staff, time
- They need to be grounded in established, evidence-based frameworks (e.g., MRC)
- PE and RE allow:
 - Enhanced interpretation of outcome evaluation results
 - Identification of facilitators and barriers for intervention delivery
 - Explanations of processes generating unexpected positive or negative intervention outcomes
 - Identification of adaptations required to achieve better contextual fit in clinical practice



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Thank you for your
attention. Any
questions?

For further info:

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