

Using Behavioural Theory and Shared Decision-Making to Understand Clinical Trial Recruitment: Interviews with Recruiters

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Background

- Strategies to improve clinical trial recruitment are often poor or highly variable in quality¹ and not typically guided by decision making and behaviour change theories
- **Shared decision-making (SDM)** is a framework designed to help people work systematically through difficult treatment decisions²
- **The Theoretical Domains Framework (TDF)** organizes over 100 constructs associated with behaviour into 12 domains, and is a comprehensive method of eliciting barriers to and drivers of health behaviours³

Methods

- We conducted **semi-structured interviews with 9 experienced study recruiters** from a target trial (StAtins for Venous Event Reduction study).
- The Interview guide included four sections:
 - 1) Ice breakers/asking about previous recruiting experience
 - 2) Asked to describe a typical recruitment encounter
 - 3) Use of constructs central to SDM (e.g. verifying understanding, clarifying preferred outcomes)
 - 4) Barriers and drivers to target trial recruitment based on the TDF
- Two coders independently reviewed and coded all interviews, meeting periodically for consensus and to revise themes and sub-themes.
- **Analysis:** Directed content analysis to assign quotations to TDF domains followed by inductive thematic analysis to identify sub-themes within domains and overarching themes.

Results

Table 1. Themes and sub-themes identified in interviews of recruiters to the target study. Sub-themes categorized according to Barriers (B) and Drivers (D), including frequency and relevant TDF domain (n=9).

Theme	Sub-theme	Freq	TDF Domain
Coordinating between people	Coordination between other recruiters and physicians is essential to success	D: 9	Behavioural Regulation
	Physicians are seen as essential to recruitment; especially reminding physicians about the study and physician buy-in	D: 9	Behavioural Regulation; Social Influences
	Recruiters rely on others to initially approach patients	D: 9	Social Influences
	Having a (non-physician) screener identify patients to recruiters	D: 7	" "
	Physicians sometimes have their own inclusion/exclusion criteria (e.g. age)	B: 1	Beliefs about Capabilities
Providing guidance to recruiters challenges	Competing studies can result in non-recruitment	B: 1	Motivation & Goals
	Recruiters say they did not receive formal training	B: 7	Skills
	Recruiters report feeling frustration/disappointment when recruitment doesn't go well	B: 6	Emotion; Beliefs about Consequences
	Recruiters feel they would benefit from training	B: 5	Skills
	Deciding not to recruit because they feel patient is not understanding the study	B: 2	Memory, Attention, Decision Process
Providing resources to recruiters	Deciding not to recruit because patient is unpleasant/aggressive	B: 2	" "
	Having recruitment goals is motivating	D: 8	Motivation & Goals
	Knowing personal recruitment numbers is helpful	D: 8	Knowledge
	Having a backup recruiter is important	D: 7	Environmental Context/Resources
	Recruiters feel they have appropriate reminders in place, and that such reminders are essential	D: 5	Memory, Attention, Decision Process
Optimizing study flow	Having access to appropriate room/space for recruitment is important	D: 7	Environmental Context/Resources
	Competing with other recruiters/sites is motivating	D: 3	Social Influences
	Insufficient time for recruitment	B: 3	Environmental Context/Resources
	Inadequate access to space	B: 2	" "
	Using visual aids (i.e. posters) to facilitate patient understanding	D: 2	Behavioural Regulation
Guiding the recruitment discussion	Visual aids were developed but unused as not REB approved	B: 2	" "
	Physical location noted as a barrier until changed for co-location with study physicians	B/D: 1	Environmental Context/Resources
	Allowing the consent forms to go home for a later decision	B:3;D:1	Nature of the Behaviour
	Time pressure felt by recruiters (1-month window)	B: 3	" "
	Requiring a consent decision right away	B: 2	" "
Emphasizing the benefits of participation	Tests required to assess eligibility sometimes interfere with time window	B: 1	" "
	Recruiters are aware of the importance of patients' understanding and ask questions to ensure they understand (informed consent)	D: 9	Behavioural Regulation
	Emphasizing the minimal burden for patients is a successful recruitment strategy	D: 4	" "
	Recruiters feel that not rushing a decision from patients is important	D: 4	" "
	Informing patients that a nurse will be readily available during the study facilitates consent	D: 7	Behavioural Regulation
Guiding the recruitment discussion	Recruiters suggest participation will provide patient with a sense of control over their condition	D: 5	" "
	Reminding patients that participation would help others	D: 4	" "
	Study design facilitates recruitment (i.e. no placebo)	D: 2	Beliefs about Capabilities

Table 2. Study recruiter responses regarding the frequency of use of elements of shared decision making during interviews (n=9).

SDM Element	Always/ Usually	Sometimes	Rarely/ Never	No response
Assessing the decision making needs of the patient?	8	1	0	
Verifying understanding?	6	3	0	
Providing information on their options, benefits, and harms (e.g., verbally or with additional patient education resources)?	9	0	0	
Clarifying their values and their attitude/tolerance towards risks?	4	3	1	1
Building their skills in deliberating, communicating, and assessing support?	1	1	7	
Facilitating progress towards decision-making?	7	1	1	
Discussing their ability/self-efficacy?	5	1	3	
Defining/explaining the decision?	8	0	0	1

Conclusion

- Results demonstrate the utility of applying the TDF and SDM lenses to shed new light on trial recruitment challenges.
- Using the TDF revealed barriers and drivers related to domains not explored by previous efforts (e.g. Skills, Nature of the Behaviour), which can be linked to evidence based approaches to behaviour change.
- Core elements of SDM are already being used by study recruiters in an ad-hoc manner and to varying degrees.
- Future research should evaluate potential interventions to address factors related to the relevant TDF domains, and provide standardized guidance and training in SDM approaches to recruiting.

References

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