

# Why patients leave clinical trials: the kidney cancer patient perspective

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## Background

Clinical trials are the cornerstone of advancing treatment for kidney cancer. Challenges with keeping patients enrolled in a trial may result in delays in completing the trial or issues with using trial findings to make decisions about clinical care.

### Objective

The objective of this pilot project was to understand the barriers kidney cancer patients face to remain on a clinical trial.

## Methods

The Theoretical Domains Framework (TDF) was used to design an interview guide and we carried out semi-structured interviews with people affected by kidney cancer who had taken part in a clinical trial to investigate factors associated with clinical trial retention. Four patients with metastatic kidney cancer from across different geographical areas were invited to take part. Two patients had left a clinical trial and two patients had remained in a clinical trial. Interviews were carried out remotely via videoconferencing. A literature review was conducted alongside the qualitative study to identify available interventions for protecting trial retention that could be applied for kidney cancer trials.

## Results

Four participants from across different geographical areas took part in the semi-structured interviews (50% of participants had completed a clinical trial and 50% had left a trial). Three participants had a diagnosis of metastatic kidney cancer and one participant was a family member of a patient with metastatic kidney cancer, who answered on behalf of the patient. Participants had taken part in a number of different kidney cancer trials ranging from phase I to phase IV, with the most common experience being participation in phase III trials for kidney cancer. Interviews were transcribed and analysed using the TDF, with the assistance of NVivo 12 software. We identified 8 domains within the TDF that were important to patient retention in clinical trials for kidney cancer and these are presented in Table 1.

## Summary of barriers and enablers for retention

Theoretical Domain (TDF)	Barrier to retention	Enabler for retention
<b>Knowledge</b> An awareness of the existence of something	<ul style="list-style-type: none"> <li>Long or complex participant information materials</li> <li>Not enough time to process participant information materials</li> <li>Low awareness of potential risks</li> </ul>	<ul style="list-style-type: none"> <li>Understanding of participation requirements</li> </ul>
<b>Social influences</b> Those interpersonal processes that can cause individuals to change their thoughts, feelings or behaviours	<ul style="list-style-type: none"> <li>Loss of trust in healthcare professional</li> <li>Scepticism of clinical trial participation from family or friends</li> </ul>	<ul style="list-style-type: none"> <li>Trust in healthcare professional</li> <li>Social support (family member; nurse; patient organisation or support group)</li> </ul>
<b>Skills</b> An ability or proficiency acquired through practice		<ul style="list-style-type: none"> <li>Sharing of experience within patient organisation or support group</li> </ul>
<b>Environmental context and resources</b> Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence and adaptive behaviour	<ul style="list-style-type: none"> <li>No travel reimbursement or complex process for travel reimbursement</li> </ul>	<ul style="list-style-type: none"> <li>Improved trial design</li> <li>Reimbursement of travel costs</li> <li>Time (e.g. not in employment)</li> </ul>
<b>Beliefs about Capabilities</b> Acceptance of the truth, reality or validity about an ability, talent or facility that a person can put to constructive use	<ul style="list-style-type: none"> <li>Distance required to travel</li> <li>Severity of side-effects</li> </ul>	<ul style="list-style-type: none"> <li>Routine study tests done locally</li> <li>Reduced number of study visits</li> </ul>
<b>Emotion</b> A complex reaction pattern, involving behavioural and physiological elements, by which the individual attempts to deal with a personally significant matter or event	<ul style="list-style-type: none"> <li>Fear and anxiety influencing decision-making</li> </ul>	<ul style="list-style-type: none"> <li>Support via family member or patient support group</li> </ul>
<b>Beliefs about Consequences</b> Acceptance of the truth, reality or validity about outcomes of a behaviour in a given situation	<ul style="list-style-type: none"> <li>Loss of quality of life</li> </ul>	<ul style="list-style-type: none"> <li>Altruism (Benefits for others; benefits to science)</li> <li>Benefits to self (Access to novel therapies or increased surveillance)</li> </ul>
<b>Reinforcements</b> Increasing the probability of a response by arranging a dependent relationship or contingency, between the response and a given stimulus	<ul style="list-style-type: none"> <li>Lack of acknowledgement</li> </ul>	<ul style="list-style-type: none"> <li>Acknowledgement</li> </ul>

Table 1. Barriers and enablers for retention from the perspective of kidney cancer patients.

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## Retention strategies for kidney cancer clinical trials

Environmental context and resources, specifically navigating travel to trial visits, was associated with high financial and emotional burden in some geographical areas. Reimbursement for travel costs and taking a patient-centred approach when planning trial visits may improve retention. COVID-19 highlighted potential means to further reduce participant burden by allowing some study tests to be conducted locally. Improving the accessibility of participant information materials may further improve trial retention. Kidney cancer patient associations can also help enable retention by increasing awareness of trials and by offering support to trial participants. Finally, sharing summaries of trial findings with participants may act as reinforcement and encourage future trial participation. A proposed model for integrating retention strategies in kidney cancer trials is presented in Figure 1.

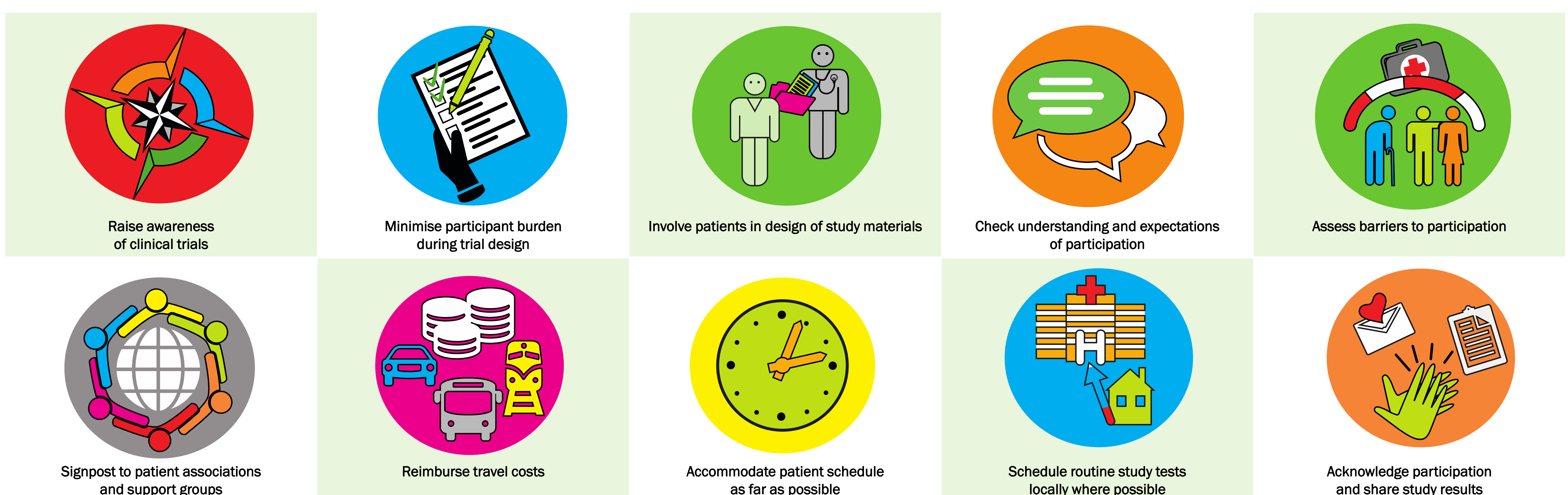


Figure 1. Model for integrating retention strategies in kidney cancer trials.

## Conclusion

This pilot project has used a theory-informed approach to identify key barriers and consequent enabling factors to consider for improving retention in clinical trials for kidney cancer. There is a need to improve awareness and access to kidney cancer trials. Improving study design to accommodate patient needs may further increase retention in kidney cancer trials. Finally, kidney cancer patient associations are an important source of information and support for trial participants. Further research to evaluate the effect of involving the kidney cancer patient community in planning and running clinical trials is needed.

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