Optimising recruitment to a TB clinical trial in Uzbekistan

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Background

The value of including social science in a randomised controlled trial is increasingly recognised within the scientific community. This study aims to understand patient and health worker experiences of the TB-PRACTECAL clinical trial (CT) by exploring patient and practitioner experiences of recruitment.

Objectives

- To understand patient and health care worker (HCW= doctor, nurse or counsellor) experiences of the TB-PRACTECAL trial recruitment process
- To explore factors perceived to impede and facilitate trial recruitment
- To explore general perceptions of clinical research
- To improve the recruitment process, creating a patient-centred approach to trial participation

Methods

Qualitative study design which employed:

- In-depth interviews with 26 participants (clinical trial patients, HCW)
- Three focus group discussions with patients, nurses and counsellors which utilised art media to co-design and develop solutions to challenges identified from the interview data
- Thematic analysis was used to analyse the data
- Limitation: no patients who refused to join the trial agreed to participate
- All participants were aged 18+ years and gave informed written consent
- This study was approved by the Ethical Committee under Ministry of Health of the Republic of Uzbekistan and by the Médecins Sans Frontières (MSF) Ethics Review Board.

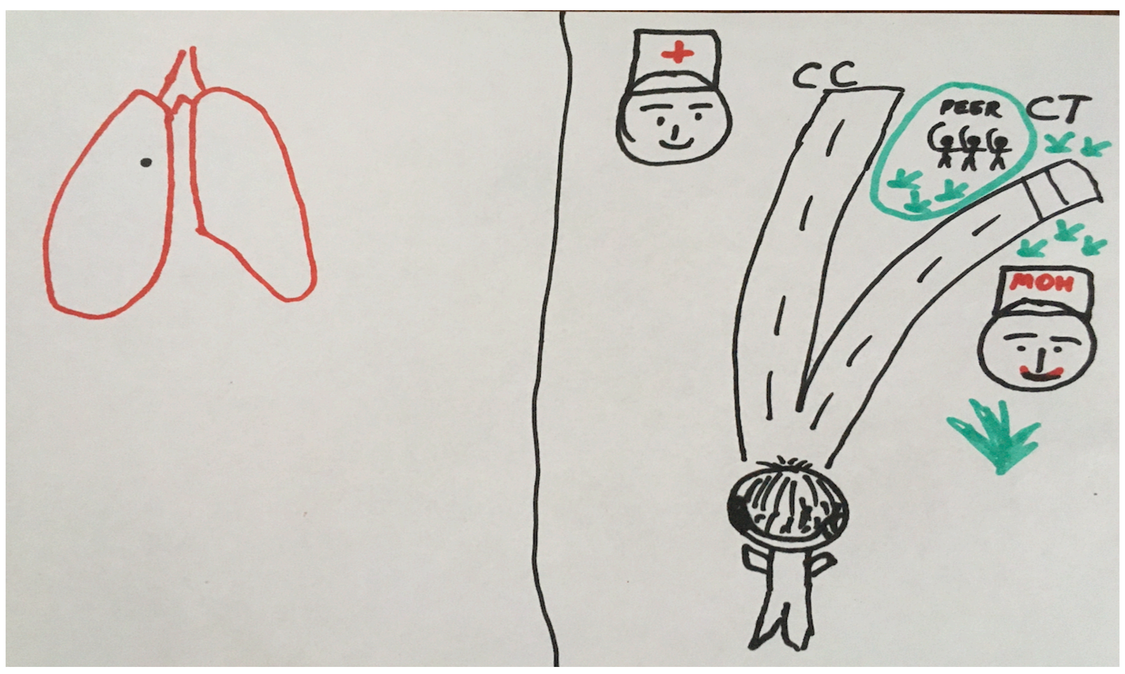
Results

- **Trust influences perceptions and engagement with the clinical trial**
  -fear and scepticism can undermine CT recruitment

"People are afraid of the clinical trial…as [clinical trial] research has never been done in Karakalpakstan before. This is something new for Karakalpakstan." FGD01, R1 (HCW)

"They might think why they are being given clinical trial, why not standard treatment? They might think they are being used…how to say this…eh…they think they are being experimented [on]." IDI21 (HCW)

"Patients play crucial role in influencing each other… They trust each other even more than us [HCW]." FGD01, R7 (HCW)



Drawing that illustrates the decision paths "CC" (Comprehensive Care = regular TB Programme) or CT (clinical trial) for a TB patient, FGD, Nukus, 2020.

- **'Seeing is believing': Hope for a better treatment supports engagement with the CT**
  -experiential evidence may reinforce trust in the CT

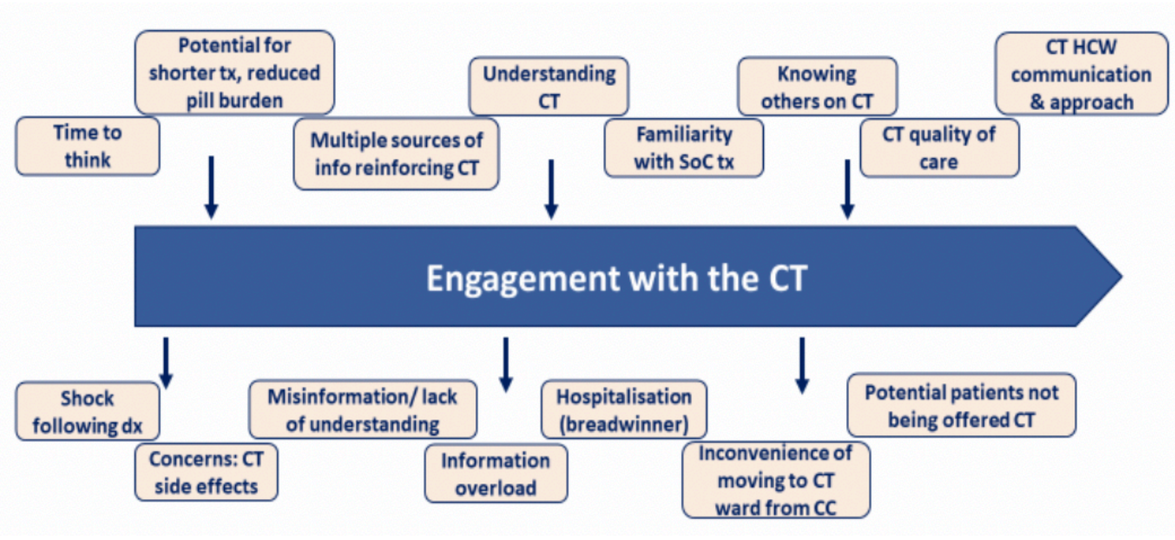
"Most people don't know [what a clinical trial is], people who have taken treatment, they know. When I stayed in hospital, most people didn't know 'clinical trial'. Counsellors are trying to explain...Those people who are not aware of it might be suspicious. But I was fine with it, didn't have any doubt. The people who have fear are those who don't have any clue about it." IDI06 (female patient)

"Another thing that I think can help… they really trust and believe if they can speak with another patient that completed the trial. Of course, I think it is impossible, you create bias, I don't know. But if they can do that, I think that can help. Because they [patients] trust their peers. Because this is somebody who passed through and completed... So, if that was possible, I think the recruitment would go up very fast." IDI13 (HCW)

"Even if we work in the same MSF together, CT girls [CT nurses] don't share the information with us. Therefore, you can imagine what they [MOH staff] think about it." FGD01, R5 (HCW)

- **Processes of engagement with the trial can both support and undermine CT recruitment**
  -The decision-making process of whether to engage with the CT are non-linear, individually and temporally varied

"I think if people don't understand that we are not experimenting on them and they have rights, they will not participate- and we need to change that attitude and perception." IDI 24, (HCW)



Key recommendations

- Enhance trust in the trial by: 1) building familiarity and understanding, 2) addressing fears and concerns, 3) sharing preliminary results with HCWs where possible, 4) supporting patients' access to see the CT ward and other CT patients, and 5) facilitating peer support opportunities

- Address issues and concerns relating to CT uncertainty and the randomisation process, which appear to be key areas influencing CT refusal

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