Capturing patient-reported experiences and quality of life outcomes in the TB-PRACTECAL clinical trial (PRACTECAL-PRO): a mixed-methods, multi-site study

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TB PRACTECAL- PRO sub study

Aim

To understand the perceptions, expectations and experiences of novel TB treatment for adult participants of TB-PRACTECAL in South Africa, Belarus and Uzbekistan

Objectives

To assess quantitatively the quality of life (QoL) of TB-PRACTECAL participants from baseline to 48 weeks: both those treated in all investigational arms and those receiving standard of care (SoC), and to compare QoL scores with local healthy controls

To describe qualitatively participant satisfaction and experience with the investigational arm trial regimens

Design, methods and participants

DESIGN

Mixed methods

METHODS

Disease specific (SGRQ) and generic (SF-12) QoL surveys

Indepth individual interviews

Literature review

PARTICIPANTS

Survey:
At least 54 in investigational arms and at least 54 in Standard of Care

108 matched Healthy controls

Indepth Interviews:
At least 54 across 3 countries

Study Population

ARM	N	GENDER (% Female)	MEDIAN AGE (Years)	IQR
Investigational Arms	96	45%	35.5	(27.0, 43.0)
Standard of Care (SoC)	41	27%	40.0	(30.0, 48.0)
Healthy Controls	134	40%	36.5	(29.0, 44.0)

S.D Standard Deviation

Comparing trial participants baseline scores with healthy control scores

	Trial participants Median (IQR)	Healthy Controls Median (IQR)	Median of the difference (95% CI)*
SGRQ Total	17.4 (7.7, 32.8)	2.4 (0.0, 5.6)	17.0 (12.9, 21.5)
SGRQ *Symptoms*	28.4 (12.7, 52.1)	2.3 (0.0, 8.9)	26.9 (19.6, 34.4)
SGRQ *Activity*	17.4 (6.2, 41.9)	0.0 (0.0, 12.2)	20.6 (14.3, 26.9)
SGRQ *Impact*	11.9 (3.7, 24.6)	0.0 (0.0, 1.6)	17.2 (13.3, 21.6)
SF-12 Physical Component Summary (PCS)	50.2 (42.4, 54.8)	56 (53.6, 57.6)	-5.3 (-7.3, -3.3)
SF-12 Mental Component Summary (MCS)	47.1 (39.5, 54.3)	54.5 (47.7, 58.8)	-6.3 (-8.9, -3.8)

IQR interquartile range
* Pseudo-median and nonparametric 95% CI

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Comparing SGRQ scores over time for investigational arm and SoC participants

For all SGRQ dimensions:

- the proportional reduction in scores per month is higher in the intervention arms versus SoC

| SGRQ	Investigational arms, estimate (95%CI)	SoC arm, estimate (95%CI)
Activity	0.86 (0.82, 0.89)	0.93 (0.88, 0.99)
Impact	0.87 (0.85, 0.90)	0.98 (0.94, 1.02)
Symptoms	0.85 (0.82, 0.88)	0.95 (0.91, 1.00)
Total score	0.87 (0.85, 0.89)	0.96 (0.92, 0.99)

For example, for symptoms:

- A participant in the intervention arm experiences a 15% reduction (95%CI 12% to 18%) in the mean score per month versus an average 5% (95%CI 0% to 9%) reduction experienced by a participant in the SoC arm
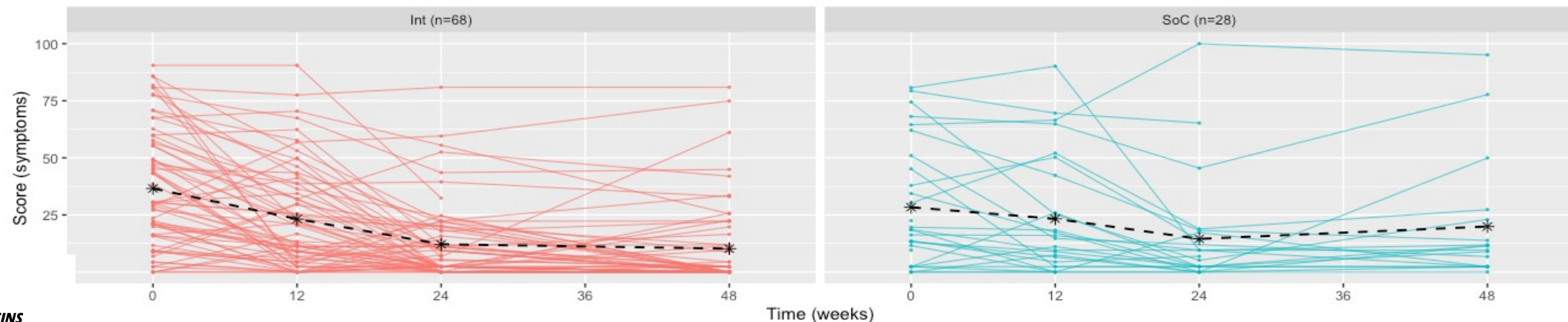
Comparing SF-12 scores over time for investigational arm and soc participants
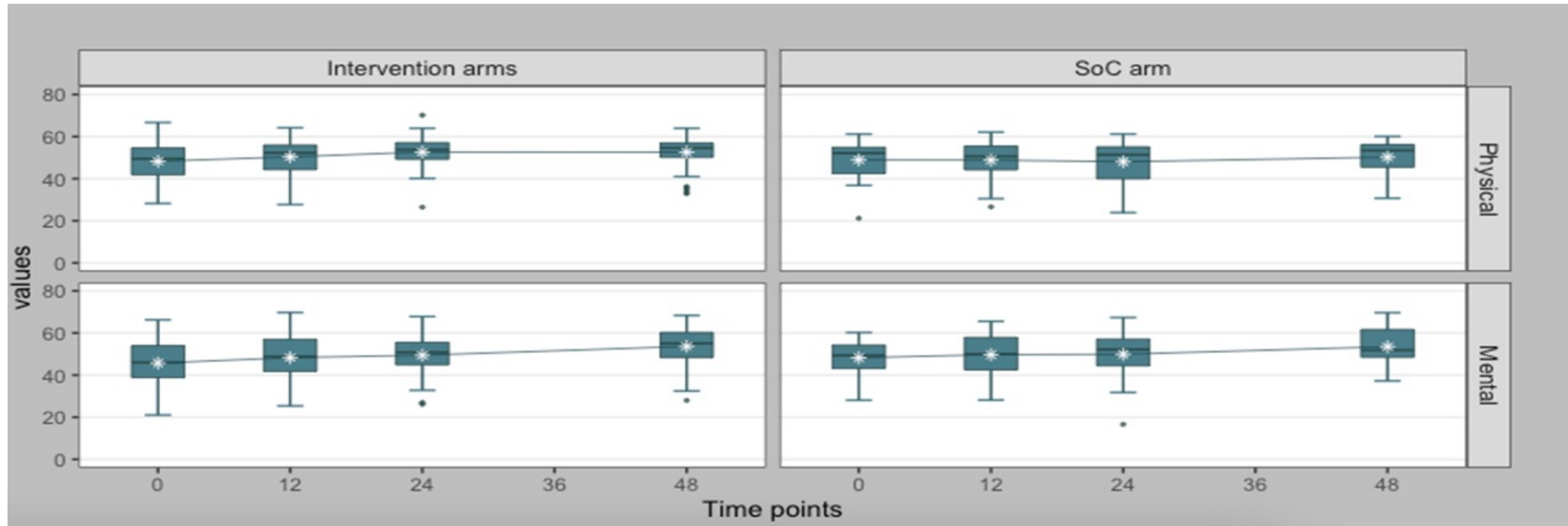
Both SF-12 scores:
- increase marginally over time (0-48 weeks)
- are similar by arm, at each timepoint (0-48 weeks)

Qualitative findings

What is important when treatment starts?

Short length of treatment

Minimal side effects

Supportive clinical care

Support from family and friends

Employment security

What is important after completing treatment?

Feeling healthy without TB

Regular clinical review and follow up care

Continuing support of family and friends

Ongoing counselling and peer support

Staying the course?

Satisfaction with and tolerability of treatment

Family and friend support increasing

General uncertainty around what the future might hold

Conclusions 1

AT BASELINE, PRACTECAL-PRO TRIAL PARTICIPANTS REPORTED A LOWER QUALITY OF LIFE THAN THE MATCHED HEALTHY CONTROL GROUP.

ALL TRIAL PARTICIPANTS RESPIRATORY-SPECIFIC QOL SCORES IMPROVED WITH TREATMENT, IRRESPECTIVE OF THE REGIMEN THEY RECEIVED. FASTER IMPROVEMENT IN THE INVESTIGATIONAL ARMS VS STANDARD OF CARE.

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Conclusions 2

Treatment acceptability was linked to participants' support networks and their experience of counselling and clinical advice.

Tolerability of the regimen helped reassure patients and household members on efficacy and value of the treatment.

Participants reported that early improvement helped them return to productive lives sooner, with the potential to address social determinants with financial protection schemes for a shorter investment period.

Patient perspectives around residual burden of disease can help inform clinicians about ongoing care.

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