



Effectiveness of the ItFits Toolkit

Christiaan Vis
On behalf of the
Effectiveness Study team (WP3):
Josien Schuurmans, Ph.D.
Claire van Genugten, MSc.
Adriaan Hoogedoorn, Ph.D.

Deliverable 3.2: Final trial report



Rationale of the ImpleMentAll project

Improving the **implementation** of evidence-based practice through
tailored implementation strategies

Implementation: deliberate and planned process of incorporating an innovation within an organization

(May, 2013, Greenhalgh et al., 2004, Eccles et al. 2009)

Tailoring: systematic process of identifying local problem, selecting and designing solution, apply and measure them



The study – research aims

- *Effectiveness study*: does the ItFits-toolkit lead to better implementation outcomes than implementation-as-usual?

And

- *Process evaluation*: to understand the mechanisms that shape implementation of the ItFits-toolkit, within and between settings.



Central *'mantra'*

*Let's get one number right
less is more*

Jeroen Ruwaard †₁₆₋₆₋₂₀₁₉



Implementation object: iCBT

- Mood disorders
- Cognitive Behavior Therapy (CBT)
- Delivered via ICT:
 - Online treatment platform
 - Self-help, therapist guided, and blended with face-to-face sessions

Organisation	Country	Prevention	Primary care	Secondary care	iCBT platform/program	Self-help	Guided	Blended
IMA0101	AL			x	iFight Depression (EAAD)		x	
IMA0201	AU	x	x		MyCompass / research platform	x		
IMA0301	DE		x		iFight Depression (EAAD)		x	
IMA0302	DE	x			Get.On / HelloBetter		x	x
IMA0401	DK			x	NoDep & Fearfighter / MindDistrict		x	
IMA0501	ES			x	Super@tuDepresión		x	
IMA0502	ES		x		Super@tuDepresión		x	
IMA0601	FR			x	MoodBuster		x	x
IMA0701	IT				iFight Depression (EAAD)		x	
IMA0801	NL		x	x	MindWay using MindDistrict			x
IMA0802	NL		x		MySelf / Master your symptoms		x	
IMA0901	XK	x		x	iFight Depression (EAAD)		x	



Assumptions and Hypothesis

Assumptions

- Implementation is object specific, contextual, takes time, and changes existing work
- Usual implementation (IAU) is generally unsystematic, intuitive, pragmatic, and often top-down oriented
- ItFits-toolkit provides a systematic, theory and evidence-informed, process for developing and applying tailored implementation strategies

Hypothesis

- Systematic and evidence-informed tailored implementation leads to better implementation outcomes than IAU does

ItFits: implementation intervention

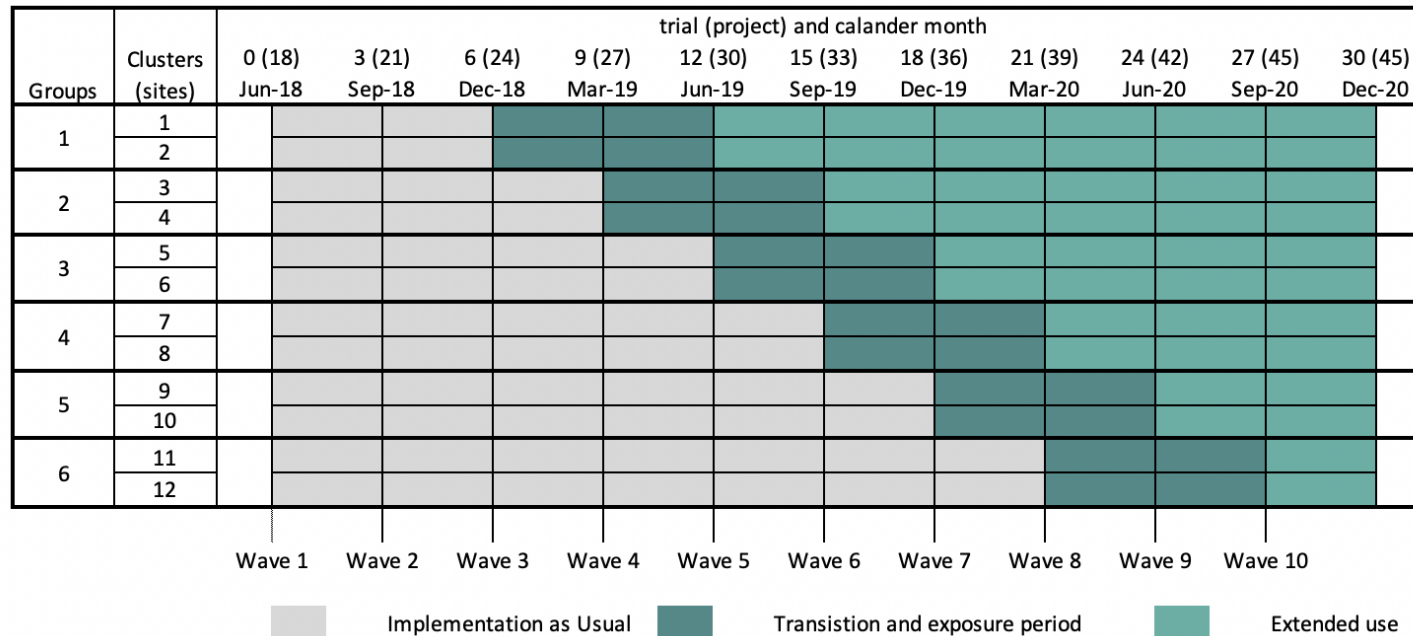
- Integrated step-by-step work process:
problem -- tailor solution -- take action -- monitor & evaluate
- Evidence-informed materials
- Six working principles
- Systematic way to work with team and stakeholders
- Various tools for collecting and storing information
- User-friendly design

What it does not do?

give the correct answer



Design: Stepped Wedge RCT



■ Primary outcome

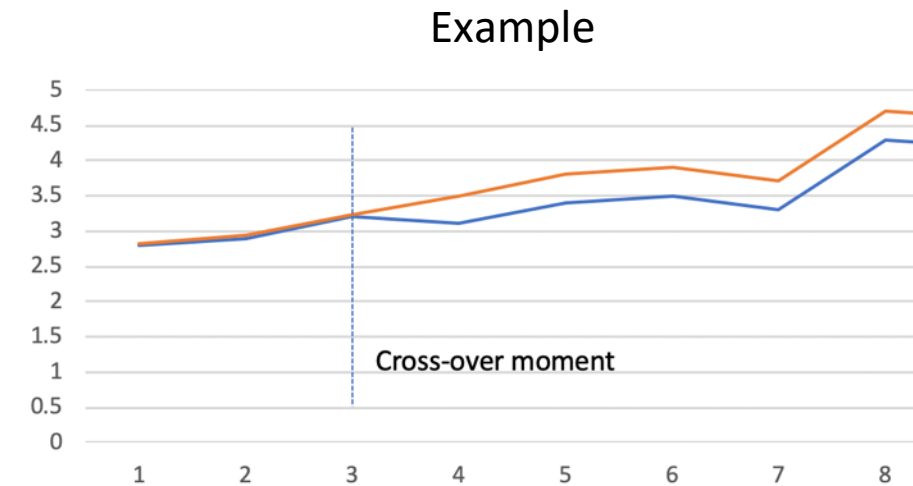
- Normalisation (May and Finch, 2009; Rapley, et al., 2018; Finch, et al., 2018)
- NoMAD: measuring implementation *processes* from the perspective of professionals
- Theory based: Normalisation Process Theory (NPT)
- 4 dimensions: sense making, relational, operational, and appraisal work
- Individual level: staff involved in iCBT delivery

■ Secondary / explorative

- Uptake of iCBT service by patients
- Implementation effort
- Both on organization / service level

Modelling Normalisation

- Staff are nested in organisations
- Generalized Linear Mixed-Effects Model
- Using within-cluster and between-cluster information
- Mixed-effects regression approach:
 - Fixed effect of time (discrete)
 - Random effect of cluster
 - Constant variation within and between clusters

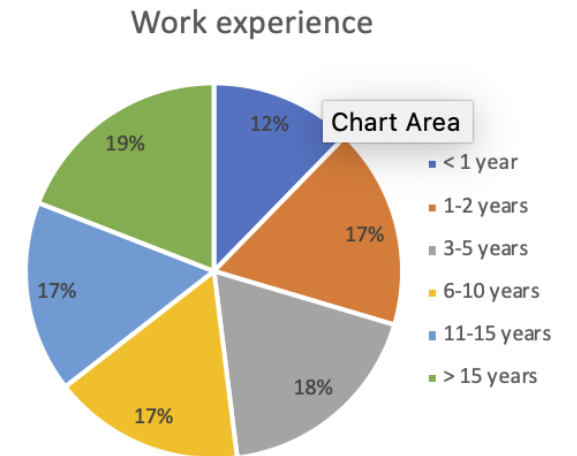
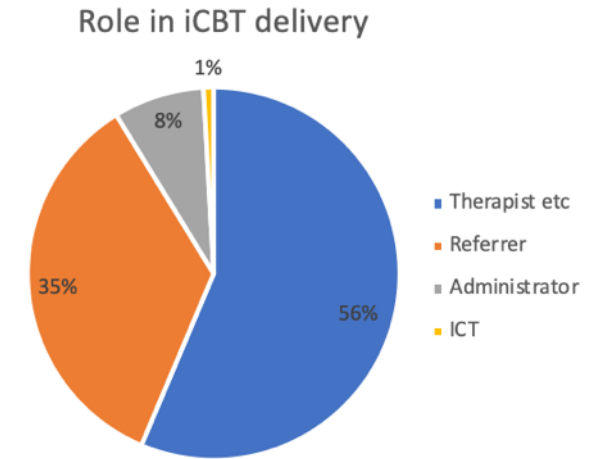


*Based on Hussey MA & Hughes JP (2007) Design and analysis of stepped wedge cluster randomized trials.
Contemporary Clinical Trials 28:182-191*

Results

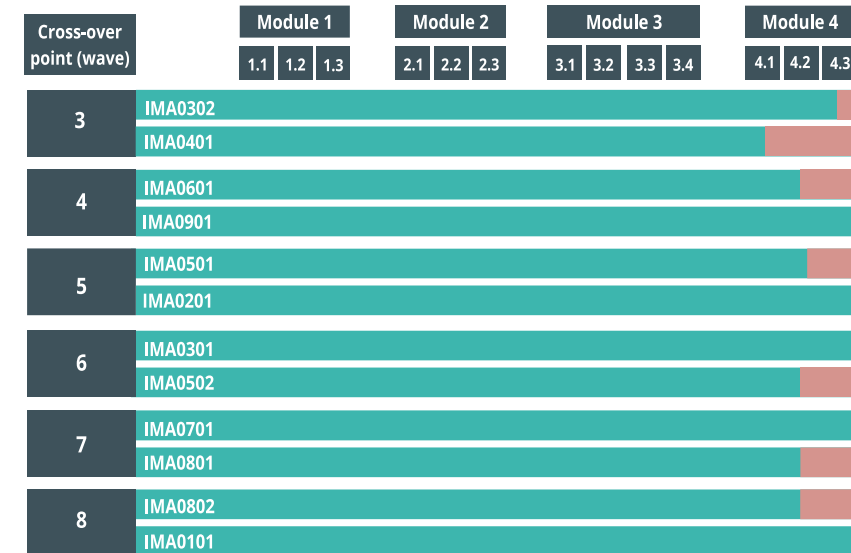
Demographics

- 39 implementers in 12 service delivery organisations used the ItFits-toolkit to implement iCBT services
- 456 iCBT unique service deliverers were followed from 09-2017 – 12-2020
 - 69% were female
 - Mean age 41 years (SD = 11.08, min-max: 18-72)
 - 74% had no prior experience with iCBT



Fidelity, exposure, and usability

- Implementation teams received
 - Introductory training
 - monthly support group calls during the exposure period
- Fidelity and exposure
 - All teams finished the toolkit within exposure period
 - Subject of Process Evaluation



ItFits status after 6 months

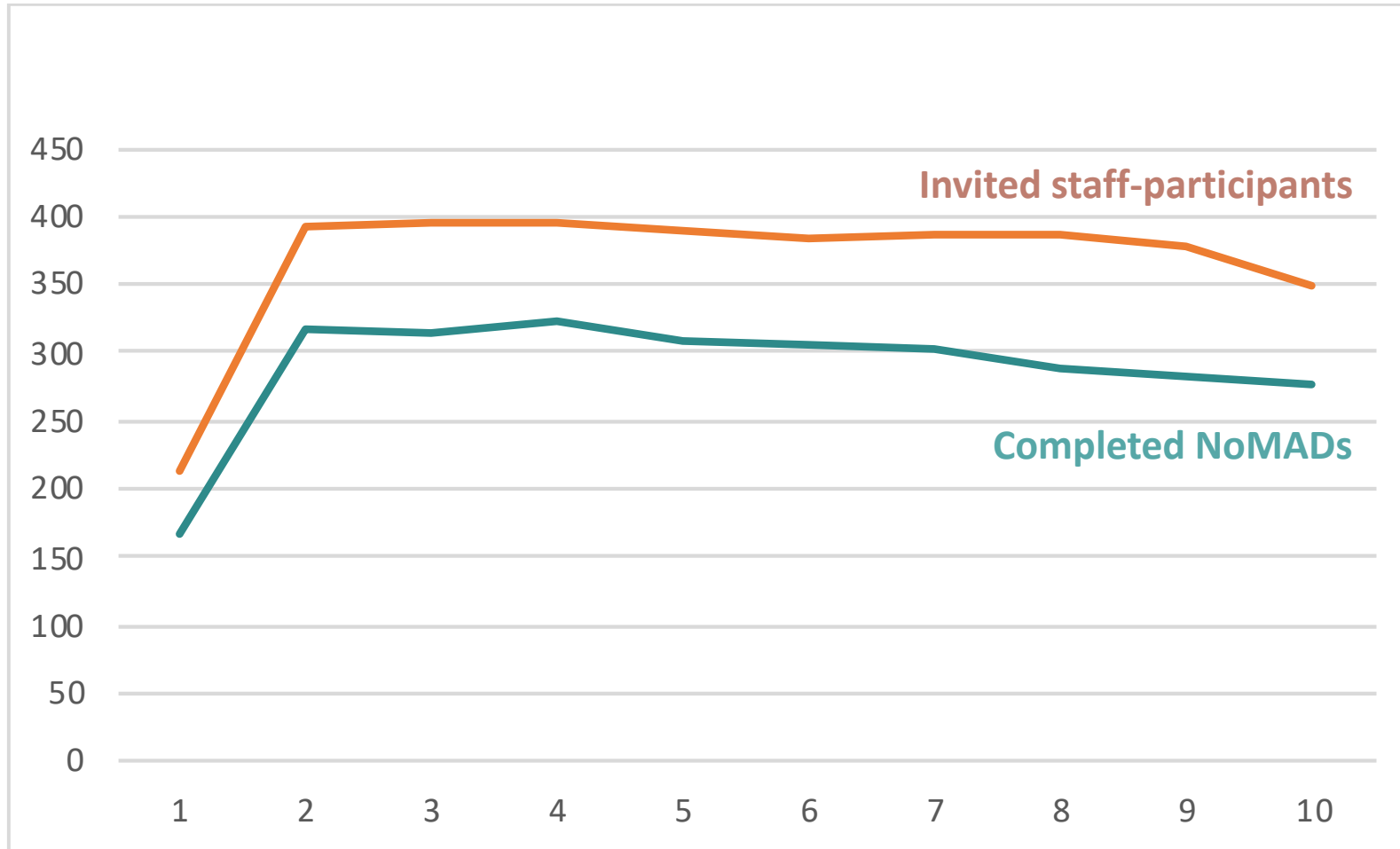
- Implementation teams were generally satisfied

($M_{\text{SUS-10}} = 77.3$, $SD = 14.2$, $\text{cut-off}_{\text{above neutral}} \geq 68$, min-max = 1-100)

- and found the toolkit usable

($M_{\text{CSQ-3}} = 7.4$, $SD = 0.9$, $\text{cut off}_{\text{above neutral}} \geq 6$, min-max = 3-12)

NoMAD response rates



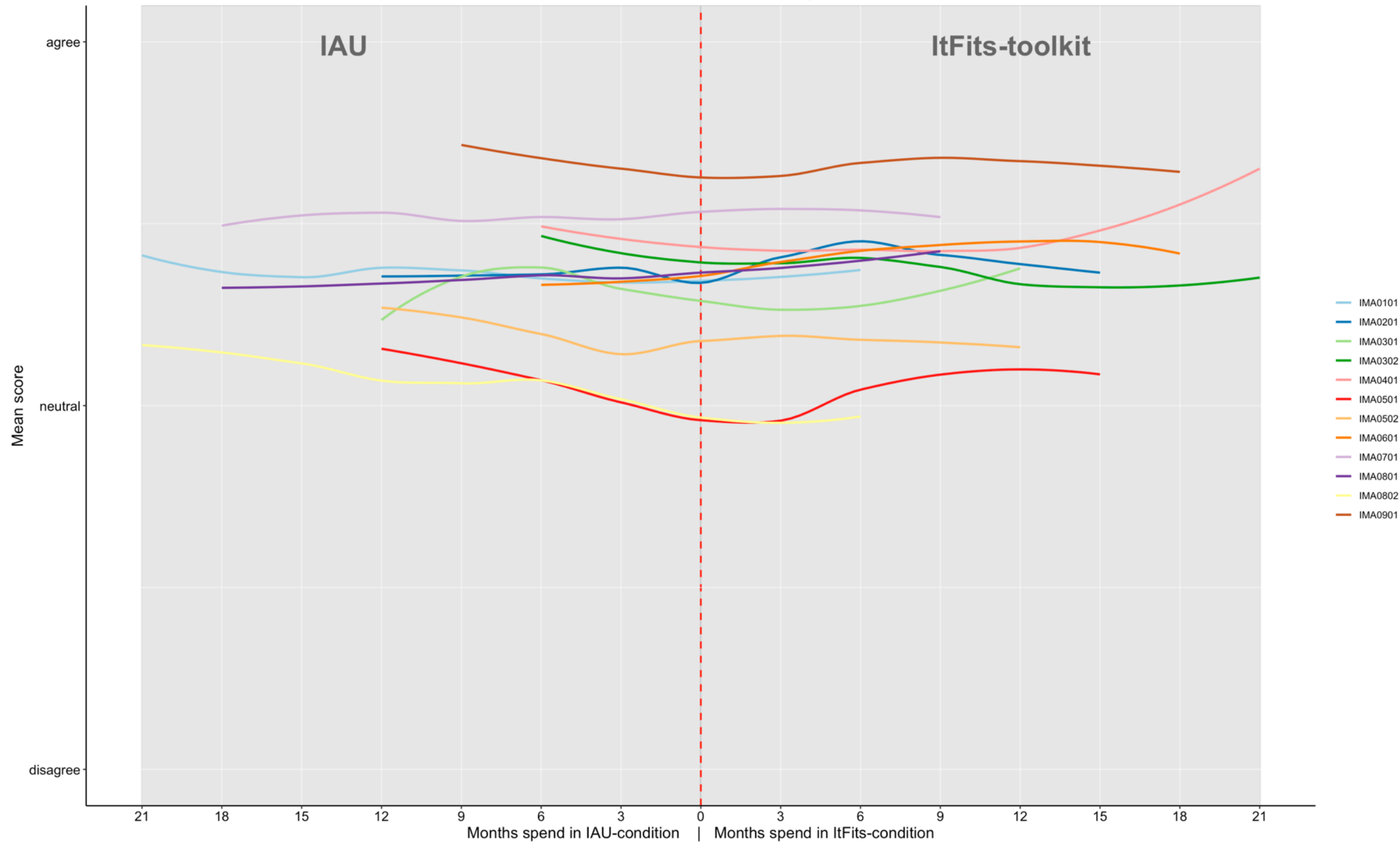
■ $N_{\text{target}} = 1,800$

■ $N_{\text{invited}} = 3,696$

■ $N_{\text{completed}} = 2,884$

■ Response rate = 78 %

Normalisation scores per organisation



Estimated effect of ItFits on Normalisation

- ItFits-toolkit has a small significant positive estimated effect

ES = 0.09; CI_{95%} = 0.01, 0.16; $t = 2.35$; $p_t = .02$; Cohen's $d = .12$

Fixed effects:

	Estimate	SD	95% CI	df	t value	Pr(> t)
Wave 1 (baseline)	3.74	0.10	3.53, 3.95	14	35.94	0.00
ItFits = TRUE	0.09	0.04	0.01, 0.16	2514	2.35	0.02

* significant change (< .05) in score relative to wave 1

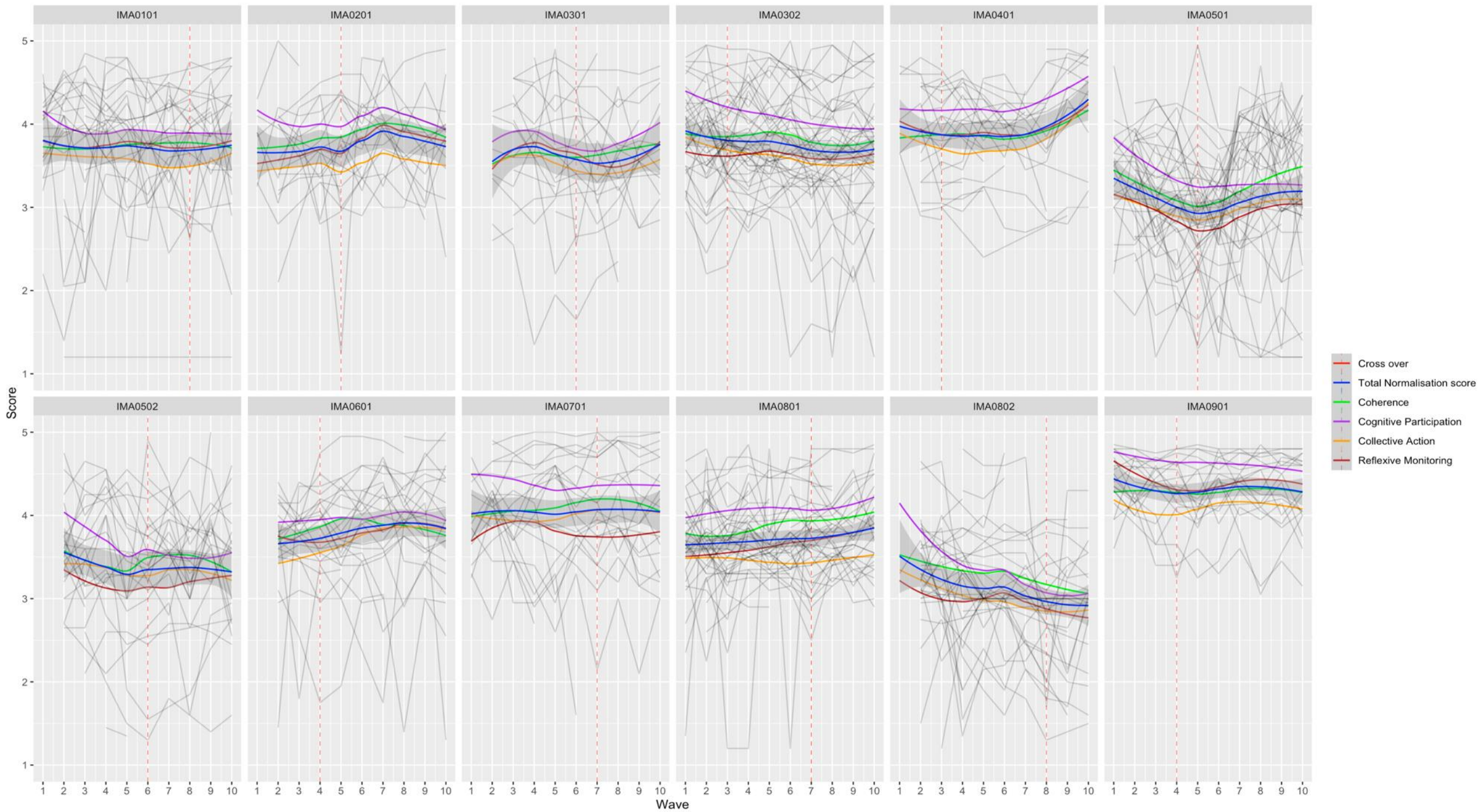
- Normalisation ~ factor(Wave) + Intervention + (1 | OrganisationID / StaffID)

where

- Intervention = .5 * (Wave > CrossOver) + .5 * (Wave > CrossOver + 1)

- Bycatch: there is a temporal effect ($\chi^2 = 25.7$, $p < 0.01$)
 - Normalisation decreases slightly over time; -0.13 points at *Wave 10*

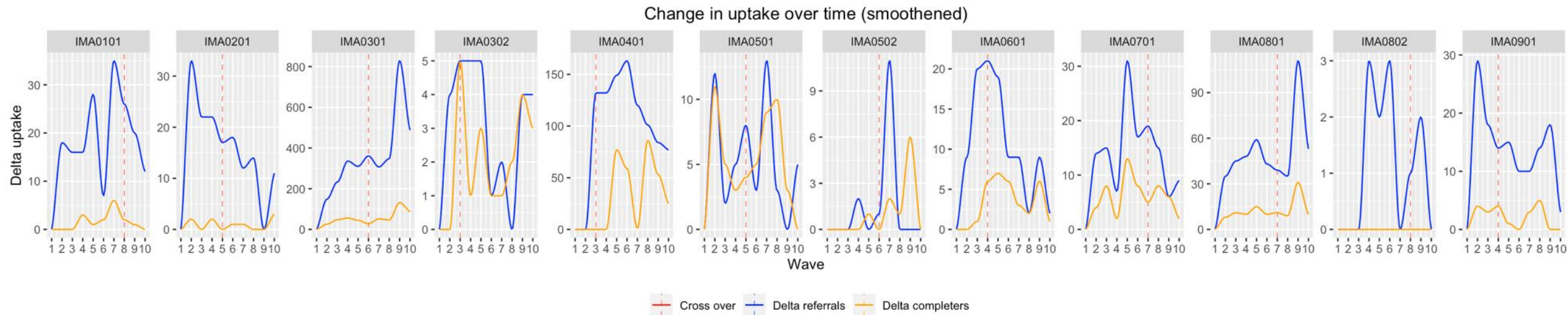
NoMAD scores



Secondary: Uptake (referrals & completers)



- Referral: to iCBT service; ie. account created
- Completer: ie. adequate exposure to iCBT
- 7,191 persons were referred to the iCBT services
- 1,430 (20%) received adequate exposure to iCBT
- 5,220 (73%) stopped their iCBT treatment prematurely



Does ItFits do better than IAU?

- Yes, but with very small effect sizes

Cohen's d of .12 and 0.09 points on a 5-point Likert scale over 30 months period

- Likely confounded with time

it is a complex, layered process

- And context dependent

'Murphy's law': reorganizations, changing legislations, ICT problems, questionnaire fatigue, natural disasters, etc.

Bigger, faster, more?

***ItFits changes, tweaks, modifies implementation,
Slowly, and not (yet) in a radical way***

If it is anything; it is modest



Discussion

- *Aggregated* effect of ItFits; piloted a *black box*
- From idea to full scale trial in one project: *large pilot study*?
- Small effect, but expected?
- Importance of *time* and '*influence*' sphere of implementers?
(eg. Wensing 2017)
- Implementation object specific; *iCBT notorious to implement*?
- Natural laboratory: *variability within reason*?
- *Theoretical implications* to normalisation and tailoring?

Results indicate it is worthwhile to take another step ! ?