Surveying knowledge, practice and attitudes toward intervention fidelity within trials of complex healthcare interventions

This study has been funded by the Irish Health Research Board Trials Methodology Research Network summer studentship awards, and is being led by researchers from the Health Behaviour Change Research Group, National University of Ireland Galway, Dr Elaine Toomey (PI) and Mr Daragh McGee (HRB-TMRN summer student). Ethical approval for this study has been granted by the Galway Clinical Research Ethics Committee.

* Required

Introduction

This survey will explore the knowledge, practice and attitudes that researchers, practitioners and others with experience of clinical trials have toward intervention fidelity in trials of complex interventions in healthcare. This is to inform future research and training needs in relation to intervention fidelity practices.

The Medical Research Council describes complex interventions as having several interacting components, e.g. number of groups targeted by the intervention, number of outcomes (Craig et al, 2008). A trial is a research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. For this study we are recruiting those with experience of trials of any complex health intervention (this excludes pharmacological/drug trials).

1	. Responses to this survey are voluntary, confidential and will not involve any personal identifying material. By participating, you are certifying that you are over the age of 18 and agreeing to allow us to anonymously publish the research ideas that you help us to identify. * Check all that apply.
	I agree
2	2. Are you or have you been directly involved (e.g. design/development, intervention delivery, data collection, evaluation) with trials of complex interventions in healthcare? (Experience as a study participant/subject only is not sufficient for the purposes of this survey) * Mark only one oval.
	Yes
	No Stop filling out this form.
3	ackground
3	3. What age are you?

	t is your gender?	
Mari	only one oval.	
	Male	
	Female	
	Other:	
5. Wha	t country do you work in?	
	only one oval.	
	Republic of Ireland	
	Northern Ireland	
	Scotland	
	Wales	
	England	
	Other:	
	PhD Masters degree Undergraduate degree MD Other:	
	t area of research are you involved with? (Tick all that ap	ply)
	Medical	
	Nursing/midwifery	
	Allied health professionals	
	Psychology	
	Public health	
	Health services research	
	Other:	

8. What best d all that apply Check all tha	
Resear	cher
Principa	al investigator
	ethodologist (someone who specializes in the methods of how trials are designed, d and reported)
Statistic	ian
Studen	t .
Epidem	iologist
Resear	ch practitioner
Practition	oner
Other:	
Delivering Data con Data are Reporting Other:	ng
you have in 11. How many y you have sp	rears of research experience do total? rears of research experience do ecific to trials of complex s in healthcare?
Knowledge 12. Are you fam Mark only on Yes	iliar with the term intervention fidelity?
O No	Skip to question 14.

Yes, I am familiar with intervention fidelity

13.	Whic		ollowing	g do yo	u think	are co	nponen	ts of int	tervent	ion fide	lity? (Ti	ck all that
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		Ensuring				to interv	ention p	roviders	is cond	lucted a	s intende	ed
		Delivering	_		_							
	Ensuring that the participant or patient has received (e.g. attended) and understood the intervention											
		Ensuring			ant is u	sing any	interver	ntion ski	lls or be	haviour	s in real	life
		None of t	he above	е								
		Other:										
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15.		well wou only one	-	lescribe	e your	underst	anding (of interv	vention	fidelity	?	
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	Poor											Excellent
	. 001											LAGOROTIL

Definition

Intervention fidelity has been described in the literature as the degree to which programmes are implemented as intended by the programme developers (Carroll et al, 2007); in other words, how true

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Practice

16. In your experience of trials of complex interventions, was intervention fidelity ever assessed (i.e. the use of strategies to assess fidelity to the intervention) or enhanced (i.e. the use of strategies to improve fidelity to the intervention)? Mark only one oval.
Yes Skip to question 17.
No Skip to question 23.
Yes, I have been involved in trials where intervention fidelity methods were used
17. Were any of these methods used to specifically assess intervention fidelity? (Tick all that apply)
Check all that apply.
Direct observation
Audio-recording
Video-recording
Provider self-report record
Provider interview (in person, or by phone)
Participant self-report record
Participant follow-up visits
Participant interview (in person, or by phone)
Exit questionnaires
None
Other:
Guidi.
 18. In your experience of trials of complex interventions, how often have strategies to assess intervention fidelity been used (on average)? Mark only one oval. 1 2 3 4 5
Never Always
19. Were any of these strategies used to enhance intervention fidelity? (Tick all that apply) Check all that apply.
Protocol review group (i.e. an expert committee to review and amend clinical protocols before implementation)
Treatment manual or scripted curriculum
Training manual (to standardize training given to those delivering the intervention)
Reminder checklists (used before delivery by those delivering the intervention)
None
Other:

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1	2	3	4	5			
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Practice

25.	In your experience of trials of complex interventions, have you ever used any of the following frameworks to inform how fidelity might be enhanced, assessed or reported)?									
	(Tick all that apply)									
	Check all that apply.									
	National Institute of Health Behaviour Change Consortium Treatment Fidelity Framework (Borrelli et al, 2005)									
	Updated National Institute of Health Behaviour Change Consortium Treatment Fidelity Framework tool (Borrelli, 2011)									
	Comprehensive Intervention Fidelity Guide (Gearing et al, 2010) Conceptual Framework for Implementation Fidelity (Carroll et al, 2007) None									
	Other:									
26.	How often do you evaluate/consider intervention fidelity practices during critical appraisal of other trials of complex interventions? Mark only one oval.									
	1 2 3 4 5									
	Never Always									
	Never									
	reporting intervention fidelity in trials of complex healthcare interventions? (Tick all that apply) Check all that apply. Poor knowledge or understanding of intervention fidelity									
	Inconsistent terminology surrounding intervention fidelity (i.e. too many synonyms)									
	Ambiguity and lack of consistency surrounding the definition of intervention fidelity (i.e. too many definitions)									
	Lack of criteria specifying acceptable levels of intervention fidelity									
	Lack of practical guidance about intervention fidelity									
	Lack of agreement regarding the most appropriate strategies of enhancement/assessment									
	Lack of perceived importance of intervention fidelity									
	Resistance/perceived resistance from those who deliver the intervention regarding the use									
	of treatment manual (e.g. limiting treatment flexibility)									
	Resistance/perceived resistance from those who deliver the intervention around monitoring/assessment									
	Core components of interventions not sufficiently identified									
	Space limitations for journal publication									
	Lack of journal requirement for publication									
	Cost									
	Time restraints									
	None									
	Other:									

add	lressing or reporting intervention fidelity in trials of complex healthcare intervention
add	ich, if any, of the following do you think may be enablers/facilitators to enhancing, Iressing or reporting intervention fidelity in trials of complex healthcare interventior k all that apply)
Che	eck all that apply.
	Clear understanding of the definition of intervention fidelity
	Good knowledge of how to assess or enhance it
	Availability of validated tools or checklists for assessment or enhancement
	Availability of practical guidance on strategies and how to adapt them to individual trials
	Perceived importance by researchers
	Perceived importance by academic journals
F	Availability of reporting criteria specific to intervention fidelity
F	Space allowances/reporting requirements within academic journals
	Accessibility of methodologists or people with skills to implement intervention fidelity
stra	tegies
	Funding or monetary resources
	Time
	Other:

Attitudes

Mark only or	s of complex interventions in healthcare?
IVIAIN OITIY OF	•
O Very	important
Impo	rtant
Unde	cided
Of litt	le importance
Not in	mportant
O Not re	elevant to my area
(Tick all tha	• • • •
Mark only or	
Neve	r
Rece	ived formal teaching (e.g. attended workshops, seminars, lectures)
Inforr	mal self directed research (e.g. self-directed reading)
Form	al research (e.g. PhD, MSc in this or related area)
Other	r:
-	avail of training in intervention fidelity if it was available?
Mark only or	ne oval.
Mark only or	Skip to question 34.
Mark only or	ne oval.
Mark only or Yes No	Skip to question 34. Skip to question 35.
Mark only or Yes No	Skip to question 34.
Mark only or Yes No	Skip to question 34. Skip to question 35.
Mark only or Yes No	Skip to question 34. Skip to question 35. d avail of training f training would you attend? (Tick all that apply)
Mark only or Yes No Yes, I woul	Skip to question 34. Skip to question 35. d avail of training of training would you attend? (Tick all that apply) at apply.
Mark only or Yes No No A. What type of Check all that	Skip to question 34. Skip to question 35. d avail of training of training would you attend? (Tick all that apply) at apply. hops
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Mark only or Yes No No A. What type of Check all that Worksh Webina	Skip to question 34. Skip to question 35. d avail of training of training would you attend? (Tick all that apply) at apply. hops ars ars
Mark only or Yes No Yes, I woul 34. What type of Check all that Worksh Webinate Seminate Lecture	Skip to question 34. Skip to question 35. d avail of training of training would you attend? (Tick all that apply) at apply. hops ars ars

Skip to question 36.

No, I would not avail of training

35. Why not? (Tick all that apply) Check all that apply.	•
I don't consider it relevant to my work	
I wouldn't have the time	
I have a good understanding of this topic already	
I don't consider it important	
Other:	
Attitudes 36. Do you have any comments you wish to add?	

Thank you!

If you have any questions or concerns, or would like to receive updates about the outcomes of this research please contact Dr Elaine Toomey by email at elaine.toomey@nuigalway.ie.

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