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Psychological interventions for epilepsy: How good are trialists at assessing their implementation fidelity, what are the barriers, and what are journals doing to encourage it? A mixed methods study

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ABSTRACT

Introduction: Psychological interventions hold promise for the epilepsy population and continue to be trialed to determine their efficacy. Such interventions present opportunities for variance in delivery. Therefore, to accurately interpret a trial's estimate of effect, information on implementation fidelity (IF) is required. We present a novel 3-part study. Part 1 systematically rated trials for the extent to which they reported assessing whether the intervention was delivered as intended (adherence) and with what sort of skill (competence). Part 2 identified barriers to reporting and assessing on fidelity perceived by trialists. Part 3 determined what journals publishing epilepsy trials are doing to support IFs reporting.
Methods: Articles for 50 randomized controlled trials (RCTs)/quasi-RCTs of psychological interventions identified by Cochrane searches were rated using the Psychotherapy Outcome Study Methodology Rating Form's fidelity items. The 45 corresponding authors for the 50 trials were invited to complete the 'Barriers to Treatment Integrity Implementation Survey'. 'Instructions to Authors' for the 17 journals publishing the trials were reviewed for endorsement of popular reporting guidelines which refer to fidelity (Consolidated Standards of Reporting Trials (CONSORT) statement or Journal Article Reporting Standards [JARS]) and asked how they enforced compliance.
Results: Part 1: 15 (30%) trials reported assessing for adherence, but only 2 (4.3%) gave the result. Four (8.5%) reported assessing for competence, 1 (2.1%) gave the result. Part 2: 22 trialists – mostly chief investigators – responded. They identified 'lack of theory and specific guidelines on treatment integrity procedures', 'time, cost, and labor demands', and 'lack of editorial requirement' as "strong barriers". Part 3: Most (15, 88.2%) journals endorsed CONSORT or JARS, but only 5 enforced compliance.
Conclusions: Most trials of psychological interventions for epilepsy are not reported in a transparent way when it comes to IF. The barriers' trialists identify for this do not appear insurmountable. Addressing them could ultimately help the field to better understand how best to support the population with epilepsy.

1. Introduction

Psychological interventions hold great potential for people with epilepsy (PWE). This is partly attributable to the high incidence of psychiatric comorbidity in the population with epilepsy [1] and the role of self-management skills [2].

Two Cochrane reviews identified 50 randomized and quasi-randomized controlled trials (RCTs) of psychological interventions for PWE [3,4]. Their methodological quality has been assessed using generic tools [5]. This has helpfully alerted readers to risks of bias in these trials and features of trial design that need improvement. Generic tools though, such as Cochrane's 2011 Risk of Bias measure [5], only provide a partial quality assessment since they do not consider other features essential to the conduct of trials of nonpharmacological treatments [6]. One feature raised by some commentators as of potential concern within epilepsy trials is the implementation fidelity (IF) [7,8].

Implementation fidelity refers to the extent to which the core content of an intervention was delivered (adherence) and with what sort of skill (competency) [9]. Assessing the IF of a psychological intervention within a trial – such as by audio-recording sessions and an independent person listening to and rating them – is important given the opportunity for variation in their implementation that comes from their often complex and multicomponent nature. Readers of a trial report require evidence from an assessment of IF to be able to accurately interpret the trial's estimate of treatment effect and to understand how and why the treatment succeeded or failed [10].

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Assessing for both aspects of IF is important since the two are not necessarily equivalent. For instance, a therapist may be highly adherent to treatment manual procedures, but is not competent in deploying them. Indeed, one skill that psychological interventions can require is for the therapist to be flexible, adapting their delivery of the intervention so as to accommodate the heterogeneity of patients' individual problems, needs, and wishes. Another reason that competence is important is that it may have a bearing on the quality of the 'therapeutic alliance' that develops between the person/s delivering the intervention and the patient. Therapeutic alliance has been suggested to be integral in determining positive therapy outcomes, potentially more so than the treatment techniques themselves [11].

If commentators' concerns regarding IF are correct, it would be important to know what barriers epilepsy trialists are facing. Standardized survey tools exist that can be used to identify them [12,13]. One barrier identified by trialists in other fields is lack of journal requirement for information on IF for a trial to be published [13]. In 2008, the Consolidated Standards of Reporting Trials (CONSORT) extension for reporting on of trials of nonpharmacological treatments became available [14], as did the American Psychological Association's Journal Article Reporting Standards (JARS) [15]. These identify the minimum set of items that need to be reported to ensure a clear and transparent account of the trial is provided. Both identify IF. Even the 2001 standard CONSORT statement asks trialists to report the extent to which participants received the intended treatment/s. It is not known though whether journals publishing epilepsy trials are encouraging, or indeed compelling, authors to follow such guidance.

This 3-part study aimed to address the aforementioned knowledge gaps. Part 1 examined the extent to which published epilepsy trials of psychological interventions assessed and reported on IF. Part 2 comprised of a cross-sectional survey examining trialists' perceived barriers to assessing and reporting on treatment fidelity. Part 3 determined the extent to which journals publishing epilepsy trials are endorsing and enforcing the use of trial reporting guidelines.

2. Methods

2.1. Part 1

2.1.1. Sample

Systematic searches completed by Ramantaran et al.'s [4] and Michaelis et al.'s [16] Cochrane reviews identified 50 trials published in full, in English between 1980 and 2016. Inclusion criteria for the reviews meant that 37 of the trials were ultimately considered by the reviews. We though considered all 50. Their mean publication year was 2009 (standard deviation [SD] = 11.9). They had been conducted in 21 countries and tested a range of interventions; typically, psychotherapeutic or educational (Table 1).

2.1.2. Assessments

Trial articles were independently rated by two reviewers (AN & SB) for the extent to which "Checks for treatment adherence" and "Checks for therapist competence" were reported. Items 16 and 17 from the reliable 'Psychotherapy Outcome Study Methodology Rating Form' (POMRF) [6] were used. For each item, a trial was categorized as 0 "poor" (no checks made), 1 "fair", or 2 "good" (frequent checks made) (see Supplementary File 1 for details, including how it was applied to trials evaluating online/automated interventions).

If a trial reported an assessment for IF had occurred, we also recorded whether any indications of the findings from the assessments were reported.

Interrater reliability for each item was assessed using the prevalence-adjusted bias-adjusted kappa (PABAK-OS) (www.singlecaseresearch.org/calculators/pabak-os). Any discrepancies in ratings were resolved through discussion.

Descriptive statistics describe the scores of the trials. Since it was in 2008 that the CONSORT extension for trials of nonpharmacological treatments and the American Psychological Association's JARS were published and identified IF, a chi-square test determined whether trials published before and after 2009 were any more likely to assess adherence and/or competence.

2.2. Part 2

2.2.1. Sample

Email addresses for the 45 corresponding authors of the 50 trials from Part 1 were sought. An invite and two reminders were sent to them (November 2018–January 2019) asking them to complete an anonymous online survey. If a valid address could not be secured, a co-author was approached.

2.2.2. Assessment

Participants completed the reliable 'Barriers to Treatment Integrity Implementation Survey' (BTIIS) [13]. Using a 6-point Likert-type scale (1 = always disagree to 6 = always agree), participants rated the extent to which they agreed with 30 different statements relating to possible impediments. Items related to A) lack of appreciation of treatment integrity; B) lack of general knowledge about treatment integrity; C) lack of theory and specific guidelines on treatment integrity procedures; D) time, cost, and labor demands; and E) lack of editorial requirement (Table 2). Participants were also asked 'how well would you describe your understanding of intervention fidelity? Participants respond using a 1 ("poor") to 10 ("excellent") scale [17].

Descriptive statistics summarize the respondents' characteristics and the extent to which they perceived the different items and domains as barriers. For the BTIIS, items with a mean rating of <3 are considered "not barriers", items with mean ratings of ≥ 3 but ≤ 4 are "barriers", and items with mean ratings of >4 "strong barriers." These cutoffs are recommended by the test developers but have not been empirically derived. Cronbach's alpha measured the BTIIS' internal reliability.

Ethical approval was granted by the University of Liverpool's Research Ethics Committee (Ref: 4085), and participants within Part 1 provided informed consent. The cross-sectional survey was conducted and reported in line with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement [18].

2.3. Part 3

2.3.1. Sample

The 17 peer-reviewed journals that had published the 50 trials from Part 1 (Table 3).

2.3.2. Methods

The 'Instructions to Authors' on the journal's websites on 11 December 2018 were examined by AN to identify whether they endorsed the use of CONSORT or JARS' guidance. As per Sims et al. [19,20], endorsement was categorized as required (essential for manuscript acceptance), recommended (usage encouraged, but not mandatory), or no mention made. Other sections of the journal's or publisher's websites referred to within the instructions were also examined. Endorsement of the International Committee of Medical Journal Editors' 'Uniform Requirements for Manuscripts Submitted to Biomedical Journals' (www.icmje.org/icmje-recommendations.pdf) and/or the Enhancing the QUAlity and Transparency Of health Research network (www.equator-network.org/) were considered equivalent to a mention of CONSORT since both endorse it.

For each journal endorsing CONSORT or JARS, the editor-in-chief and/or editorial office were sent an invitation email and two reminders (December 2018–January 2019) asking them whether they had a policy to enforce the use of the guideline they endorsed. As per Hopewell et al. [21], a policy was defined as any systematic

Table 1
Summary of 50 trials of psychological interventions and extent to which they assessed and reported on implementation fidelity.

Trial	Year	Country	Intervention		POMRF			
			Delivery	Type	Adherence		Competence	
					Rating	Result reported	Rating	Result reported
Aliasgharpour et al.[S1]	2013	Iran	Educational	In person	Poor	–	Poor	–
Au et al.[S2]	2003	China	Psychotherapy (CBT)	In person	Poor	–	Poor	–
Beretta et al.[S3]	2014	Italy	Educational	In person	Poor	–	Poor	–
Caller et al.[S4]	2016	US	Self-management & cognitive training	In person	Fair	No	Poor	–
Ciechanowski et al. [S5]	2010	US	Psychotherapy (CBT)	In person	Fair	No	Poor	–
Dahl et al.[S6]	1985	Sweden	Psychotherapy (relaxation behavioral therapy)	In person	Poor	–	Poor	–
Dahl et al.[S7]	1987	Sweden	Relaxation therapy	In person	Poor	–	Poor	–
Dash et al. [S8]	2015	India	Educational	In person	Poor	–	Poor	–
Davis et al.[S9]	1984	US	Psychotherapy (CBT)	In person	Poor	–	Poor	–
Dilorio et al.[S10]	2011	US	Self-management	Online	Fair	No	N/A	N/A
Dilorio et al.[S11]	2009	US	Self-management	In person	Good	No	Fair	No
Earl [S12]	1986	US	Psychotherapy (family therapy)	In person	Poor	–	Poor	–
Fraser et al.[S13]	2015	US	Self-management	In person	Poor	–	Poor	–
Gandy et al. [S14]	2014	Australia	Psychotherapy (CBT)	In person	Good	No	Fair	No
Gillham [S15]	1990	Scotland	Self-management & counseling	In person	Fair	No	Poor	–
Helde et al. [S16]	2005	Norway	Educational & counseling	In person	Poor	–	Poor	–
Helgeson et al.[S17]	1990	US	Educational	In person	Poor	–	Poor	–
Hosseini et al.[S18]	2016	Iran	Psychotherapy (CBT)	In person	Fair	No	Fair	No
Jantzen et al.[S19]	2009	Germany	Educational	In person	Poor	–	Poor	–
Lantz & Sterman [S20]	1988	US	EEG biofeedback	In person	Poor	–	Poor	–
Lewis et al.[S21]	1990	Chile	Educational	In person	Poor	–	Poor	–
Li et al. [S22]	2016	China	Psychotherapy (family therapy)	In person	Poor	–	Poor	–
Lua & Neni [S23]	2013	Malaysia	Educational	Phone	Poor	–	Poor	–
Lundgren et al. [S24]	2006	S. Africa	Psychotherapy (ACT)	In person	Poor	–	Poor	–
Lundgren et al.[S25]	2008	India	Psychotherapy (ACT)	In person	Fair	No	Poor	–
Martinović et al.[S26]	2006	Serbia	Psychotherapy (CBT)	In person	Poor	–	Poor	–
May & Pfäfflin [S27]	2002	Germany, Austria, Switzerland	Educational	In person	Poor	–	Poor	–
McLaughlin & McFarland [S28]	2011	Australia	Psychotherapy (CBT)	In person	Poor	–	Poor	–
Modi et al.[S29]	2016	US	Adherence intervention (problem solving)	In person	Poor	–	Poor	–
Nagai et al.[S30]	2004	UK	Galvanic skin response biofeedback	Partly by computer	Fair	No	Poor	–
Olley et al. [S31]	2001	Nigeria	Educational	In person	Poor	–	Poor	–
Orjuela-Rojas et al.[S32]	2015	Mexico	Psychotherapy (CBT)	In person	Fair	No	Poor	–
Pakpour et al.[S33]	2015	Iran	Adherence intervention (motivational interviewing)	In person	Good	Yes	Good	Yes
Peterson et al.[S34]	1984	Australia	Adherence intervention (counseling and medication support reminders)	In person	Poor	–	Poor	–
Pfäfflin et al.[S35]	2012	Germany, Switzerland	Educational	In person	Poor	–	Poor	–
Pfäfflin et al.[S36]	2016	Germany	Educational	In person	Poor	–	Poor	–
Pourmohamadreza et al.[S37]	2015	Iran	Psychotherapy (attribution retraining)	In person	Poor	–	Poor	–
Pramuka et al. [S38]	2007	US	Educational	In person	Poor	–	Poor	–
Puskarich et al.[S39]	1992	US	Relaxation therapy	In person	Poor	–	Poor	–
Ridsdale et al. [S40]	2000	UK	Educational	In person	Poor	–	Poor	–
Rousseau et al.[S41]	1985	US	Relaxation therapy	In person	Poor	–	Poor	–
Schröder et al.[S42]	2014	Germany	Psychotherapy (CBT)	Online	Fair	No	N/A	N/A
Sterman & Shouse [S43]	1980	US	EEG biofeedback	Partly by computer	Fair	No	N/A	N/A
Synder [S44]	1983	US	Relaxation therapy	In person	Poor	–	Poor	–
Tan & Bruni [S45]	1986	Canada	Psychotherapy (CBT)	In person	Fair	Yes	Poor	–
Tang et al. [S46]	2015	China	Psychotherapy (mindfulness-based therapy)	In person	Poor	–	Poor	–
Thompson et al. [S47]	2015	US	Psychotherapy (mindfulness-based therapy)	Online & phone	Good	No	Poor	–
Thompson et al.[S48]	2010	US	Psychotherapy (mindfulness-based therapy)	Online & phone	Poor	–	Poor	–
Tieffenberg et al. [S49]	2000	Argentina	Self-management	In person	Poor	–	Poor	–
Yadegary et al.[S50]	2015	Iran	Educational	In person	Poor	–	Poor	–

Notes: Type of intervention derived from by Ramantaran et al.'s and Michaelis et al.'s Cochrane reviews; ACT, acceptance and commitment therapy; CBT, cognitive behavioral therapy; EEG, electroencephalogram; POMRF, Psychotherapy Outcome Study Methodology Rating Form (adherence and competence items each scored on scale of "poor", "fair" and "good"; N/A = domain of 'competence' not applicable because of the nature of the intervention tested within this trial (see Supplementary File 1 for further details); bibliography for this table is found in Supplementary File 2.

action to enforce adherence to the reporting standard — such as all articles being screened by the editorial office upon submission or acceptance for adherence to CONSORT/JARS and revisions requested, or changes being made by the assistant editors of these journals towards the end of the editorial process. Journals could respond by email or via an online survey. We did not consider relying on peer reviewers to identify adherence to CONSORT/JARS policy, unless they were specifically instructed to assess and report on it. This was because a policy implies an action that is deployed consistently, and it is known that peer reviewers are not necessarily unanimous in their views and often fail to identify missing information [22].

Table 2
Mean ratings for items in Barriers to Treatment Integrity Implementation Survey and classification.

Barrier domain	Survey item	Mean (SD)	Barrier classification
C	6) The literature does not agree as to what is the appropriate method of fidelity assessment.	4.79 (0.78)	Strong barriers
D	16) It is expensive and time consuming to provide direct training to those delivering the intervention (e.g., viewing therapy tapes, providing feedback, having regular meetings with staff, role-playing techniques).	4.63 (1.60)	
D	12) Designing and validating fidelity measures is labor intensive and time consuming.	4.42 (1.53)	
E	30) There is a lack of editorial insistence/enforcement on the need to implement fidelity procedures.	4.42 (1.12)	
C	2) There is an inconsistency in the terminology of the aspects of treatment fidelity (e.g., treatment adherence, therapist competence, treatment differentiation).	4.37 (1.01)	
C	9) The definition of treatment fidelity in the literature is ambiguous.	4.26 (0.80)	
C	14) There are no conventional criteria that specify acceptable levels of treatment fidelity.	4.26 (1.14)	
C	29) Therapist competence is not clearly defined in the literature.	4.21 (1.13)	
D	18) There is a considerable time requirement in obtaining accurate representation of fidelity data (collection of data across therapists, situations, cases, and sessions).	4.21 (1.27)	
C	21) There are no established criteria or principles by which treatment fidelity may be judged.	4.16 (1.06)	
E	26) Most treatment outcome research articles are accepted without fidelity being adequately addressed.	4.11 (1.15)	
D	22) High labor costs may preclude researchers from employing or training fidelity raters.	4.00 (1.15)	Barriers
E	3) Journal editors do not require the description of fidelity procedures for the article to be accepted.	4.00 (1.49)	
D	7) Insufficient resources due to the constrained funding from grants hinder the adequate implementation of fidelity procedures.	3.95 (1.35)	
B	23) Treatments are presumed to be effective if significant changes on the dependent measures are obtained regardless of the level treatment fidelity.	3.79 (1.51)	
E	4) Because there are no specific requirements for reporting fidelity, just mentioning that fidelity was monitored without providing quantitative information is regarded as sufficient.	3.74 (1.28)	
C	15) The guidelines for evaluating psychometric properties (validity and reliability) of the treatment fidelity measures are unclear.	3.74 (1.32)	
E	5) Careful implementation and assessment of fidelity are not necessary to get a study published.	3.68 (1.60)	
E	19) Limited journal space precludes adequate reporting of fidelity procedures.	3.63 (1.06)	
B	28) It is generally believed that fidelity procedures can be implemented primarily with behavioral interventions but not with other approaches, such as psychodynamic or interpersonal treatments.	3.47 (1.17)	
B	10) The requirements of internal review boards hinder implementation of fidelity procedures (e.g., limiting how data are handled and linked to specific therapists, pushing for audio instead of videotaping).	3.42 (1.07)	
B	11) Treatments are not sufficiently manualized to permit adequate fidelity implementation.	3.37 (1.30)	
B	13) Once established, treatment fidelity is believed to be stable and not to fluctuate over time.	3.26 (1.32)	
B	20) Performing checks on fidelity of treatment may be risky as fidelity may be lower than desired (e.g., credibility of results may be compromised by reporting low levels of integrity).	3.16 (1.21)	
A	8) Report of the treatment fidelity procedures is not considered to enhance the credibility of the treatment outcome results.	3.11 (1.37)	
B	24) Treatment manuals are not widely employed because they are thought to limit therapist flexibility in addressing clients' problems and tailoring of treatment to the individual needs.	2.95 (1.26)	Not barriers
B	17) Those delivering interventions resist close supervision and monitoring of treatment fidelity.	2.79 (1.61)	
A	1) Treatment fidelity is not regarded as imperative for ensuring adequate experimental control.	2.47 (1.26)	
A	27) The cost of implementing fidelity procedures outweighs the possible benefits.	2.47 (1.34)	
A	25) Once the training of the therapists is completed, supervision and monitoring of treatment fidelity does not justify the time and labor costs.	2.00 (1.05)	

Notes: Items with mean rating of ≤3 are considered "not barriers"; items with mean rating of >3 and ≤4 are considered "barriers"; and items with mean rating of >4 are considered "strong barriers". Domain A) lack of appreciation of treatment integrity; B) lack of general knowledge about treatment integrity; C) lack of theory and specific guidelines on treatment integrity procedures; D) time, cost, and labor demands; and E) lack of editorial requirement.

3. Results

3.1. Part 1

3.1.1. Interrater reliability

Substantial agreement existed between raters. For item 16 (adherence), they gave the same rating for 90% of trials (PABAK-OS = 0.85; 95% confidence interval [CI]: 0.72, 0.98). For item 17 (competence), it was the same for 84% (PABAK-OS statistic of 0.76; 95% CI: 0.63, 0.89).

3.1.2. Quality rating

Of the 50 trials, 15 (30%) reported monitoring for adherence to some extent, with 2 (4.3%) also giving an indication of the result. Of the 47 trials for which competence was applicable, only 4 (8.5%) reported

Table 3
Journals that published the 50 trials testing psychological interventions and extent they endorse and enforce use of trial reporting guidance.

Journal name	Impact factor	Number of trials from Part 1 published	Do 'Instructions to Authors' refer to reporting standards?	Which?	Strength of endorsement?	Enforcement policy?
Clinical Neurophysiology[a]	3.61	1 (2.0)	Yes	CONSORT	Recommended	No
Cognitive Behaviour Therapy	2.80	1 (2.0)	No	–	–	–
Epilepsy & Behavior	2.60	17 (34.0)	Yes	CONSORT	Recommended	No
Epilepsia	5.07	17 (34.0)	Yes	CONSORT	Recommended	Yes
Iranian Red Crescent Medical Journal	0.79	1 (2.0)	Yes	CONSORT	Recommended	Yes
Journal of Behavioral Medicine	2.88	1 (2.0)	Yes	CONSORT	Recommended	Yes
Journal of Clinical Psychology	2.33	1 (2.0)	Yes	JARS	Recommended	No
Journal of Consulting & Clinical Psychology	4.54	1 (2.0)	Yes	JARS	Recommended	Yes
Journal of Neuroscience Nursing	0.95	1 (2.0)	Yes	CONSORT	Recommended	No
Journal of Telemedicine & Telecare	3.05	1 (2.0)	Yes	CONSORT	Recommended	No
Journal of Urban Health	1.74	1 (2.0)	No	–	–	–
Journal of Neurology, Neurosurgery & Psychiatry	7.14	1 (2.0)	Yes	CONSORT	Recommended	No response
Neurology	8.06	1 (2.0)	Yes	CONSORT	Required	Yes
Patient Education & Counseling	2.79	1 (2.0)	Yes	CONSORT	Recommended	No response
Psychiatry Investigation	1.43	1 (2.0)	Yes	CONSORT	Recommended	No
Psychological Reports	0.67	1 (2.0)	Yes	CONSORT	Recommended	No
Seizure	2.84	2 (4.0)	Yes	CONSORT	Recommended	No
			15/17 (88.2)		1/15 (6.7%)	5/13 (38.5%)

Notes: Impact factor for journals is based on Web of Knowledge impact factor for 2017; as per Sims et al. [19], words or phrases such as "should", "prefer", "encourage", "in accordance with the recommendation of", and "expected" were rated as 'recommended', while words or phrases such as "must", "need", or "manuscripts will not be considered for publication unless" were regarded as 'required'. Where it was unclear, a journal was categorized as 'recommended', rather than 'required'.
[a] Previously named *Electroencephalography and Clinical Neurophysiology*.

assessing it; 1 (2.1%) gave an indication of the result (Table 1). Only one trial [23] reported assessing both adherence and competence and provided the results.

Proportionally, more trials (n = 10; 40%) published since 2009 had assessed adherence and/or competence compared to those published before (n = 5; 20%). This difference was not statistically significant (Fisher exact: P = 0.217).

3.2. Part 2

3.2.1. Sample

Twenty-two authors responded to the survey, indicating a response rate of ~49%. Two respondents started the survey, but did not finish the BTISS, and so, analyses focused on the 20 respondents with complete data.

The 20 respondents were located in 8 different countries and had a median of 13 years of experience conducting trials of psychological interventions (interquartile range [IQR] = 8–23.75). All but one held a research degree (19; 95%), and most obtained their highest qualification in Western Europe or the United States (n = 12; 60%). Most rated their understanding of fidelity to be high (median 8: IQR = 7–9; mean = 7.53; SD = 2.23), and most (n = 14; 70%) had been a trial's chief investigator.

Cronbach's alpha for the BTIIS was 0.89, indicating high internal consistency.

3.2.2. Perceived barriers

Of the 30 BTIIS items, 11 (36.7%) had mean ratings indicating that they were "strong barriers". Of the remaining, 14 (46.7%) were categorized as "barriers" and 5 (16.7%) as "not barriers" (Table 2).

The items endorsed as "strong barriers" came from the following three domains: C) lack of theory and specific guidelines on treatment integrity procedures; D) time, cost, and labor demands; and E) lack of editorial requirement (Supplementary File 2).

3.3. Part 3

3.3.1. Sample

The 17 journals had a median impact factor of 2.8 (IQR: 1.58, 4.07). Most trials (n = 34; 68%) were published within two of the journals – namely, *Epilepsia* and *Epilepsy and Behavior*.

3.3.2. Results

All but two journals (n = 15; 88.2%) endorsed CONSORT or JARS. Only one journal (6%) though used wording to indicate adherence to the guideline was 'required', rather than 'recommended' (Table 3).

Of the 15 journals endorsing CONSORT or JARs, 13 (86.7%) responded to our survey. Of these, 5 (38.5%) reported having an enforcement policy. *Epilepsia* and *Epilepsy and Behaviour* both 'recommended' the reporting guidelines, but only *Epilepsia* reported an enforcement policy.

4. Discussion

4.1. Main findings

A basic requirement of a trial report is that it conveys, in a complete and transparent way, the trial's conduct and findings. Knowing whether the tested intervention was delivered as intended is one fundamental piece of information that readers require. Our systematic assessment found that most trials of psychological interventions in epilepsy are not providing this information. There has been some improvement with time. Nevertheless, the majority of contemporary trials are still not providing the information.

The proportion of epilepsy trials that reported assessing adherence (i.e., 30%) and competence (i.e., 8.5%) is broadly within the range documented for trials evaluating psychological interventions for other groups. Using the same scale, reviews have found that 13–23% of trials in the wider mental health literature have assessed adherence and 0–16% competence [24–27]. We contend that this should be not be seen as reassuring since most of the epilepsy trials were categorized as having assessed adherence or competence had not used particularly rigorous methods. Most received only a 'fair', rather than a 'good' rating.

What explains the low proportion of trials reporting IF assessments? Is it that interventions being trialed are not conducive to IF assessments? No, this is not the case. Around 40% of the trials tested skills-based interventions, such as cognitive behavioral therapy (CBT) and acceptance and commitment therapy (ACT). These can be readily organized into treatment manuals and IF tested. About a third of the trials did evaluate interventions using supportive-educational approaches (e.g., psychoeducation). These interventions can value therapist flexibility and the making of adjustments to an intervention on the basis of the

individual receiving it (e.g., motivation for change, learning style) [28]. This though does not preclude IF assessment. Studies show that such interventions can be operationalized (without undermining them) and their IF assessed [29–31].

We surveyed trial authors to help elucidate the reasons for them not assessing and reporting IF. We did this as the wider literature shows that the barriers reported by trialists are associated with how well they assess IF within their published trials [13]. Approximately, half of the trialists invited responded to our survey – a response rate in line with prior survey research in this area [12,13,17]. Most respondents had been a trial chief investigator.

The findings from the survey can be seen as somewhat positive. Firstly, respondents identified slightly fewer "strong barriers" to fidelity assessment and reporting than trialists in other fields when they were given the BTIIS [13]. Secondly, respondents tended to appreciate the importance of treatment fidelity and rated their understanding of it to be high. In fact, with a mean score of 7.53, they rated their understanding to be higher than trialists of complex interventions generally (mean: 5.84) [17]. Thirdly, the items which were perceived by our respondents to be "strong barriers" clustered into 3 domains, and these do not appear to be insurmountable – namely, and in descending order of importance, the lack of theory and specific guidelines on treatment integrity procedures; the time, cost, and labor demands; and finally, the lack of editorial requirement.

4.2. How to improve things

The first strong barrier identified by the survey was the lack of theory and specific guidelines on treatment integrity procedures. Historically, disagreement has existed regarding the key theoretical elements contributing to intervention fidelity. Varied language has also been used [12]. This has perhaps created confusion, and means' trialists are unclear as to what to assess. We would though like to draw trialists' attention to the National Institutes of Health's Behavior Change Consortium latest 40-item fidelity framework [32]. It brings some welcomed clarity to the topic by synthesizing research and providing a comprehensive conceptual model of fidelity. It identifies five aspects of fidelity that can be used by trialists to guide efforts to enhance and monitor treatment fidelity. These are study design, training of intervention providers, IF (intervention delivery), receipt of intervention, and enactment of skills (the extent to which participants apply the skills learnt).

That trialists identified a lack of specific guidance as a strong barrier is perhaps unsurprising. Guidelines on fidelity have been published (e.g., [33]).These tend though to be general, providing minimal guidance on how to actually do it. It is pleasing therefore to note that several practical examples comprising step-by-step guidance on assessing IF are now available (e.g., [29,34]). These could provide trialists with practical templates to follow.

Authors have an ethical and professional responsibility to conduct their trials to the highest possible standards and to report it accurately and transparently. The findings from the survey indicate though that other stakeholders also have a role. The second domain trialists identified as being a strong barrier to fidelity assessment was, for instance, the time, cost, and labor demands associated with fidelity. Addressing and assessing fidelity does come at an additional cost, and thus, resources will be required to allow fidelity assessments to occur.

Securing research funding is a competitive process. It might be tempting to not include or remove a fidelity assessment from a trial project to make it cheaper and more fundable – not least because the trial's outward appearance will remain the same. We would though urge funders to consider that any savings generated by this practice are outweighed by the negative scientific and societal costs of not giving attention to treatment fidelity. Indeed, the cost of assessing IF is not always substantial. Ridsdale et al. [35] recently completed a definitive RCT of a self-management group intervention for PWE. The IF of 3 of the intervention's core modules was evaluated by two raters. They budgeted £2700 (~3500 US$) for this. In the context of a ~£1.5 million (~1.9 US$; www.journalslibrary.nihr.ac.uk/programmes/hta/0916501/#/) trial, this is negligible, not least because the findings have allowed accurate interpretation of the trial's null effect.

To facilitate change, funders could provide a specific section within grant applications where applicants must state how they shall address fidelity. Some UK and US funders have used this approach to encourage change in other aspects of trial conduct (e.g., trial registration, involvement of clinical trial units, and service user representatives). Alternatively, how fidelity is to be monitored within a planned trial might be described as part of a formal "process evaluation" that might be conducted alongside the trial. Such evaluations are increasingly being advocated to help trial's address questions beyond efficacy, such as intervention feasibility, mechanisms of change, and the quantity and quality of what was delivered [33].

Trialists' responses to the survey indicated that journals also have an important role in supporting change. Respondents identified that a current lack of editorial requirement for assessing and reporting on treatment integrity within a trial for it to be published was a strong barrier. We assessed the instructions for authors of journal's publishing epilepsy trials and contacted editorial offices. Most journals did endorse the use of reporting guidelines that note the importance of providing IF information, although in many cases compliance with such guidelines was not mandatory. Journals publishing epilepsy trials are not unique in this regard [19,20].

In recent years, different initiatives aimed to improve compliance with reporting guidelines for trials have been proposed [36]. Several, such as WebCONSORT which is a writing support tool for authors [37], have been evaluated and found to not lead to meaningful improvements in quality of reporting. Arguably, a more promising approach is the active enforcement of guideline compliance by journals [21,38]. Their gatekeeper role means that they are uniquely positioned to stipulate what authors must include within their reports. Hopewell et al. [21] compared the effect of completeness of reporting of trial abstracts after the release of CONSORT guidance. Guidelines only improved reporting when actively implemented by a specific editorial policy – such as emailing authors to revise the abstract according to CONSORT guidance at the revision stage.

We found that only a handful of journals publishing epilepsy trials currently have active enforcement policies in place. We would encourage more to adopt one. Case examples of how journals can do this have been published [39]. One example is the Journal of Pediatric Psychology [40]. Since 2017, all submissions to this journal of trial reports undergo an additional transparent reporting review by a Student Editorial Liaison. We recognize that not all journals have the same resources and some journals may be reluctant to introduce a process that could deter submissions (e.g., [41]). Enforcement could though lead to the publication of more articles which offer high quality evidence, and which attract more citations.

4.3. Strengths and limitations

The findings of our study should be seen in the context of potential limitations. Firstly, we focused only on intervention delivery. While some consider this to be the "heart" of fidelity [42], it does, as pointed out by the National Institutes of Health's Behavior Change Consortium framework [32], form only one aspect of fidelity. We cannot comment on how well trials addressed the other fidelity aspects.

Secondly, we considered trials published up until 2016. It is not clear how well our findings reflect current practice. While the assessment and reporting of IF within contemporary trials in our study remained generally poor, it had improved over time. We are aware of 6 RCTs of psychological interventions published since 2016 [35,43–47]. Only two have hitherto assessed and reported on IF [30,31].

Thirdly, on a related point, we assessed IF in trials identified by two Cochrane reviews [3,4]. Those reviews were primarily set up to identify

trials which had quality of life as an outcome measure. Also, a number of trials conducted within the pediatric field were not captured by the two reviews. Al-aqeel et al. [48] have published a Cochrane review of trials of psychological interventions for PWE that had medication adherence as the outcome measure. Wagner et al. [49] and Lewis et al. [50] have conducted reviews focused on pediatric epilepsy self-management trials. These 3 reviews identified 11 trials of psychological type interventions for PWE that were not captured by the searches of Ramantaran et al. and Michaelis et al. We assessed IF within them and found that their exclusion from the sample of trials considered by Part 1 did not meaningfully change the findings since IF practices within them were also poor. Specifically, of the 11 trials, 3 (27%) assessed adherence, but none gave an indication of the result. Two (22%) assessed competence to some extent, with 1 giving an indication of the result. Supplementary File 4 shows the findings in detail.

Fourthly, our study was not able to determine the relationship between the barriers to IF reporting and assessment which trial authors perceived to exist and the extent to which they reported on IF within their own trial reports. This was because trialists completed the Part 2 survey anonymously, and so, it was not possible to link their responses to their articles. We speculated that if participation was not anonymous, some trialists might have been reluctant to take part and acknowledge potentially low knowledge of, or confidence in, IF.

Finally, not all trialists contacted responded to our survey invitation. While common with such surveys, it is possible that responders and nonresponders differ in important ways. This could limit the generalizability of our findings.

5. Conclusions

Most trials of psychological interventions for epilepsy are not reporting information on the fidelity with which the tested intervention was delivered. Barriers identified by authors for this appear addressable and include the need for clearer guidance on how to assess fidelity and support from funders for resources. Journals also appear to have a role to play in requiring trials to report on the extent to which interventions were delivered as intended. Currently, most journals recommend it, but do not enforce the requirement for clear and transparent reporting of IF.

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Declaration of competing interest

None of the authors has any conflict of interest to disclose.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.yebeh.2019.05.041.

References

[1] Kerr MP, Mensah S, Besag F, de Toffol B, Ettinger A, Kanemoto K, et al. International consensus clinical practice statements for the treatment of neuropsychiatric conditions associated with epilepsy. Epilepsia 2011;52:2133–8.
[2] Helmers SL, Kobau R, Sajatovic M, Jobst BC, Privitera M, Devinsky O, et al. Self-management in epilepsy: why and how you should incorporate self-management in your practice. Epilepsy Behav 2017;68:220–4.
[3] Michaelis R, Tang V, Wagner JL, Modi AC, LaFrance WCJ, Goldstein LH, et al. Psychological treatments for people with epilepsy Cochrane Database of Syst Rev. 2017;10: CD012081.
[4] Ramaratnam S, Baker GA, Goldstein LH. Psychological treatments for epilepsy. Cochrane Database Syst Rev 2008(16):CD002029.
[5] Higgins PT, Green S, Altman GD, Sterne JAC. Assessing risk of bias in included studies. In: Higgins JP, Green S, editors. Cochrane handbook for systematic reviews of interventions version 5.1.0 the Cochrane collaboration; 2011.
[6] Ost LG. Efficacy of the third wave of behavioral therapies: a systematic review and meta-analysis. Behav Res Ther 2008;46:296–321.
[7] Modi AC, Wagner J, Smith AW, Kellermann TS, Michaelis R. Implementation of psychological clinical trials in epilepsy: review and guide. \Epilepsy Behav 2017;74: 104–13.
[8] Noble AJ, Reilly J, Temple J, Fisher PL. Cognitive-behavioural therapy does not meaningfully reduce depression in most people with epilepsy: a systematic review of clinically reliable improvement. J Neurol Neurosurg Psychiatry 2018;89:1129–37.
[9] Cross WF, West JC. Examining implementer fidelity: conceptualizing and measuring adherence and competence. J Child Serv 2011;6:18–33.
[10] Carroll C, Patterson M, Wood S, Booth A, Rick J, Balain S. A conceptual framework for implementation fidelity. Implement Sci 2007;2:40.
[11] Messer SB, Wampold BE. Let's face facts: common factors are more potent than specific therapy ingredients. Clin Psychol Sci Pract 2002;9:21–5.
[12] Hagermoser Sanetti LM, DiGennaro Reed FD. Barriers to implementing treatment integrity procedures in school psychology research: survey of treatment outcome researchers. Assess Eff Interv 2012;37:195–202.
[13] Perepletchikova F, Hilt LM, Chereji E, Kazdin AE. Barriers to implementing treatment integrity procedures: survey of treatment outcome researchers. J Consult Clin Psychol 2009;77:212–8.
[14] Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P, Group C. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. Ann Intern Med 2008;148:295–309.
[15] APA Publications and Communications Board Working Group on Journal Article Reporting Standards. Reporting standards for research in psychology: why do we need them? What might they be? Am Psychol 2008;63:839–51.
[16] Michaelis R, Tang V, Wagner JL, Modi AC, LaFrance WCJ, Goldstein LH, et al. Psychological treatments for people with epilepsy. Cochrane Database Syst Rev 2017(10): CD012081.
[17] McGee D, Lorencatto F, Matvienko-Sikar K, Toomey E. Surveying knowledge, practice and attitudes towards intervention fidelity within trials of complex healthcare interventions. Trials 2018;19:504.
[18] von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. Lancet 2007;370:1453–7.
[19] Sims MT, Henning NM, Wayant CC, Vassar M. Do emergency medicine journals promote trial registration and adherence to reporting guidelines? A survey of "Instructions for Authors". Scand J Trauma Resusc Emerg Med 2016;24:137.
[20] Sims MT, Bowers AM, Fernan JM, Dormire KD, Herrington JM, Vassar M. Trial registration and adherence to reporting guidelines in cardiovascular journals. Heart 2018;104:753–9.
[21] Hopewell S, Ravaud P, Baron G, Boutron I. Effect of editors' implementation of CONSORT guidelines on the reporting of abstracts in high impact medical journals: interrupted time series analysis. Br Med J 2012;344:e4178.
[22] Bruce R, Chauvin A, Trinquart L, Ravaud P, Boutron I. Impact of interventions to improve the quality of peer review of biomedical journals: a systematic review and metaanalysis. BMC Med 2016;14:85.
[23] Pakpour AH, Gholami M, Esmaeili R, Naghibi SA, Updegraff JA, Molloy GJ, et al. A randomized controlled multimodal behavioral intervention trial for improving antiepileptic drug adherence. Epilepsy Behav 2015;52:133–42.
[24] Öst LG. The efficacy of acceptance and commitment therapy: an updated systematic review and meta-analysis. Behav Res Ther 2014;61:105–21.
[25] Öst LG, Havnen A, Hansen B, Kvale G. Cognitive behavioral treatments of obsessive-compulsive disorder. A systematic review and meta-analysis of studies published 1993-2014. Clin Psychol Rev 2015;40:156–69.
[26] Finnes A, Enebrink P, Ghaderi A, Dahl J, Nager A, Öst LG. Psychological treatments for return to work in individuals on sickness absence due to common mental disorders or musculoskeletal disorders: a systematic review and meta-analysis of randomized-controlled trials. Int Arch Occup Environ Health 2019;92:273–93.
[27] Hedman-Lagerlöf M, Hedman-Lagerlöf E, Öst LG. The empirical support for mindfulness-based interventions for common psychiatric disorders: a systematic review and meta-analysis. Psychol Med 2018;48:2116–29.
[28] Perepletchikova F, Treat TA, Kazdin AE. Treatment integrity in psychotherapy research: analysis of the studies and examination of the associated factors. J Consult Clin Psychol 2007;75:829–41.
[29] Mars T, Ellard D, Carnes D, Homer K, Underwood M, Taylor SJ. Fidelity in complex behaviour change interventions: a standardised approach to evaluate intervention integrity. BMJ Open 2013;3:e003555.
[30] Noble AJ, Snape D, Ridsdale L, Morgan M, Nevitt SJ, Goodacre S, et al. Assessing treatment fidelity within an epilepsy randomized controlled trial: seizure first aid training for people with epilepsy who visit emergency departments. Behav Neurol 2019; 66:1–11.
[31] Wojewodka G, Hurley S, Taylor SJ, Noble AJ, Ridsdale L, Goldstein LH. Implementation fidelity of a self-management course for epilepsy: method and assessment. BMC Med Res Methodol 2017;17:100.
[32] Borrelli B. The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. J Public Health Dent 2011;71:S52–63.
[33] Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. Br Med J 2015; 350:h1258.
[34] Toomey E, Matthews J, Guerin S, Hurley DA. Development of a feasible implementation fidelity protocol within a complex physical therapy-led self-management intervention. Phys Ther 2016;96:1287–98.
[35] Ridsdale L, Wojewodka G, Robinson EJ, Noble AJ, Morgan M, Taylor SJC, et al. The effectiveness of a group self-management education course for adults with poorly controlled epilepsy, SMILE (UK): a randomized controlled trial. Epilepsia 2018;59: 1048–61.
[36] Blanco D, Kirkham JJ, Altman DG, Moher D, Boutron I, Cobo E. Interventions to improve adherence to reporting guidelines in health research: a scoping review protocol. BMJ Open 2017;7:e017551.
[37] Hopewell S, Boutron I, Altman DG, Barbour G, Moher D, Montori V, et al. Impact of a web-based tool (WebCONSORT) to improve the reporting of randomised trials: results of a randomised controlled trial. BMC Med 2016;14:199.

[38] Park E, Tudiver F, Campbell T. Enhancing partner support to improve smoking cessation. Cochrane Database Syst Rev 2012(7).
[39] EQUATOR Network. Case studies: how journals implement reporting guidelines; 2010.
[40] Hildenbrand AK. Editorial: enhancing transparent reporting of pediatric psychology intervention research: introducing the role of the student editorial liaison. J Pediatr Psychol 2018;43:5–7.
[41] Elizabeth W, Peter W. "Hardly worth the effort"? Medical journals' policies and their editors' and publishers' views on trial registration and publication bias: quantitative and qualitative study. Br Med J 2013;347:f5248.
[42] Gearing RE, El-Bassel N, Ghesquiere A, Baldwin S, Gillies J, Ngeow E. Major ingredients of fidelity: a review and scientific guide to improving quality of intervention research implementation. Clin Psychol Rev 2011;31:79–88.
[43] Haut SR, Lipton RB, Cornes S, Dwivedi AK, Wasson R, Cotton S, et al. Behavioral interventions as a treatment for epilepsy: a multicenter randomized controlled trial. Neurology 2018;90:e963–70.
[44] Sajatovic M, Colon-Zimmermann K, Kahriman M, Fuentes-Casiano E, Liu H, Tatsuoka C, et al. A 6-month prospective randomized controlled trial of remotely delivered group format epilepsy self-management versus waitlist control for high-risk people with epilepsy. Epilepsia 2018;59:1684–95.
[45] Meyer B, Weiss M, Holtkamp M, Arnold S, Brückner K, Schröder J, et al. Effects of an epilepsy-specific internet intervention (Emyna) on depression: results of the ENCODE randomized controlled trial. Epilepsia 2019. https://doi.org/10.1111/epi.14673 [Epub ahead of print].
[46] Leenen LAM, Wijnen BFM, Kessels AGH, Chan H, de Kinderen RJA, Evers SMAA, et al. Effectiveness of a multicomponent self-management intervention for adults with epilepsy (ZMILE study): a randomized controlled trial. Epilepsy Behav 2017;73:64–70.
[47] Noble AJ, Marson AG, Tudur-Smith C, Morgan M, Hughes DA, Goodacre S, et al. 'Seizure first aid training' for people with epilepsy who attend emergency departments, and their family and friends: study protocol for intervention development and a pilot randomised controlled trial. BMJ Open 2015;5:e009040.
[48] Al-aqeel S, Gershuni O, Al-sabhan J, Hiligsmann M. Strategies for improving adherence to antiepileptic drug treatment in people with epilepsy. Cochrane Database Syst Rev 2017(2):CD008312.
[49] Wagner JL, Modi AC, Johnson EK, Shegog R, Escoffery C, Bamps Y, et al. Self-management interventions in pediatric epilepsy: what is the level of evidence? Epilepsia 2017;58:743–54.
[50] Lewis SA, Noyes J, Hastings RP. Systematic review of epilepsy self-management interventions integrated with a synthesis of children and young people's views and experiences. J Adv Nurs 2015;71:478–97.