Title: Discerning the adverse effects of psychological therapy: consensus between experts by experience and therapists.

Short title: **Adverse effects of psychological therapy**

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Abstract

Measurement of adverse effects of psychological therapy is inconsistent due to ambiguity about the concept. The perspective of people undertaking psychological therapy (that is, experts by experience) has largely been overlooked. This study will investigate whether there is consensus between the opinions of professionals and experts by experience. The Delphi method was used. In Round 1 thematic analysis was used to analyse qualitative responses. Wilcoxon rank-sum tests were used to examine group differences in Rounds 2 and 3. The study protocol was prospectively registered, reference osf.io/f9wp7. Fifty-one professionals and 51 experts by experience generated 147 potential adverse effects in Round 1, across 9 themes; including "therapy amplifies problem", "emotional lability" and "sense of self". Each item was rated for overall consensus in Rounds 2 (n=62) and 3 (n=63). Thirty-eight items were rated as essential, very important or important to include on a list of potential adverse effects. A further 12 items were rated as important by the expert by experience group only. Professionals were more conservative in their ratings. There appeared to be consensus between professionals and experts by experience on what to include in a list of adverse effects of psychological therapy (the EDAPT), including novel adverse effects which have not been previously considered. Further research is required to understand which adverse effects are necessary, unnecessary, or indeed harmful to psychotherapy outcomes.

Key Practitioner Message

- There is growing recognition of the importance of acknowledging adverse effects within psychological therapy to support informed consent, however there is no consensus on the potential adverse effects of psychological therapy.
- In this study a panel of experts by experience and professional therapists created a comprehensive list of adverse effects and ranked how important it was to consider each item.
- This list, the EDinburgh Adverse effects of Psychological Therapy (EDAPT) may be used as a teaching tool and to guide clinical discussion. Further research is required to create an outcome measure.
- This study highlighted that therapist ratings of adverse effects are more conservative than ratings of experts by experience.

Introduction

Adverse effects are widely acknowledged when applying pharmacological interventions, and open and transparent reporting of these is essential for informed patient decision-making and consent to treatment (NICE, 2011). At present, much less is known about the possible adverse effects of engaging with psychological therapy (henceforth referred to as therapy), yet an emerging evidence base indicates that there may be significant personal cost and discomfort (Crawford et al., 2016; Linden, 2013; Parry et al., 2016; Vaughan et al., 2014). Reports indicate that between 3 and 10% of people may "worsen" after therapy (Berk & Parker, 2009; Crawford et al., 2016) and there is a growing recognition by therapists that negative effects exist (Berk & Parker, 2009; Bystedt et al., 2014). There is no consensus on the definition of adverse effects, and in this context the term refers to effects of therapy that are unwanted, uncomfortable or harmful. The creation of a transdiagnostic, trans-therapeutic definition would allow for direct comparison across therapeutic modalities, and, identify "if there would be another therapy that works without this… [this] would be better' (Linden, 2013).

Measuring Adverse Effects

Research on the adverse effects of pharmacological interventions report that between a third and a half of patients do not spontaneously report when they experience adverse effects, thus patient-report questionnaires are recognised as essential in identifying adverse effects (Foster et al., 2008). Therapy involves not only the therapeutic approach and patient factors, but also therapist factors (Waller & Turner, 2016). The power imbalance inherent to the therapist-patient relationship has been identified as a potentially key contributor to adverse effects (Berk & Parker, 2009; Linden & Schermuly-Haupt, 2014; Parry et al., 2016) and may further preclude spontaneous reporting of adverse effects, especially if it is perceived to relate to the therapist and/or the therapeutic relationship. As with assessment of therapy benefits, use of standardised

instruments may help to mitigate potential under-reporting, and allow for a more accurate assessment of potential harms.

Clarity on what patients and therapists identify as necessary or indeed, acceptable, adverse effects may also help to reduce "therapist drift" (Waller & Turner, 2016), which may arise due to therapist avoidance of effective intervention methods that are perceived to be adverse for patients, such as exposure in anxiety interventions, or trauma-focused interventions (Sars & van Millen, 2015; Waller & Turner, 2016). Clarity may also increase the ability to distinguish harmful effects from uncomfortable, and the necessary from the unnecessary. There are some untested beliefs about therapy; what level of discomfort is necessary to the process, or that things need to 'get worse before they get better' (Department of Health, n.d.). Agreed upon definitions of potential adverse effects may support investigation of such beliefs. Indeed, two studies found that early adverse effects may impede efficacy or lead to lesser improvement, which challenges the assumption of 'no pain no gain' (Lutz et al., 2013; Moritz et al., 2015).

Measures of adverse effects of psychological therapy have been published (see Table 1 for an overview and comparison of characteristics), however some focus more on the risk factors for adverse effects (Berk & Parker, 2009; Bystedt et al., 2014; Linden & Schermuly-Haupt, 2014; Parry et al., 2016). Indeed, the Experiences of Therapy Questionnaire (ETQ; Parker et al., 2013) and Unwanted Event to Adverse Treatment Reaction (UE-ATR; Linden, 2013) are perhaps best described as measures of negative therapeutic processes, whereas the Inventory for the assessment of Negative Effects of Psychotherapy questionnaire (INEP; Ladwig et al., 2014) and Negative Effects Questionnaire (NEQ: Rozental et al., 2016) focus on the potential adverse effects as experienced by the patient. The INEP items were generated from a literature review and the opinions of therapy professionals, while the NEQ items were generated from a literature review, expert consensus, and qualitative data from online interventions of social

anxiety. Thus, generalisability may be limited as the sample included only groups with social anxiety undertaking an online intervention.

Table 1; Characteristics of measures of adverse effects of psychological therapy

	ETQ	UE-ATR	NEQ	INEP	SEPS	TOH[1]
Scale Characteristics						
Items generated from; Literature	+	+	+	+	+	.
; Expert opinion	-	-	+	+	+	.
; Patient opinion	-	-	+	-	-	.
Examined with patients (n)	707	0	653	195	85	.
Number of items (n)	63	16	32	21	97	.
Self (S) or clinician (C) rated	S	C	S	S	S	.
Scale type (Likert/Checklist (CL))	Likert	CL	CL	Likert	Likert	.
Attribution of effects to therapy		+	+	+		+
Process Issues	+	+	+	+	+	+
Adverse effects						
"Negative wellbeing"		+				
Interpersonal difficulty		+		+		+
Work impacted/sick leave		+		+		
Deterioration		+			+	
Emotion/symptoms		+	+	+	+	+
"Behavioural deterioration"						+
Hopelessness			+			
Failure; sense of incompetence			+			
Stigmatisation		+	+	+		
Dependency			+	+		+
Mortality						+
Reoffending						+
Preoccupation with therapy	+					

ETQ: Experiences of Therapy Questionnaire; Parker et al, 2013. UE-ATR: Unwanted Event to Adverse Treatment Reaction Checklist; Linden, 2013. NEQ: Negative Effects Questionnaire; Rozental et al, 2016. INEP: Inventory for the assessment of Negative Effects of Psychotherapy questionnaire; Ladwig et al, 2014. SEPS: Side Effects of Psychotherapy Scale; Moritz, 2015 (combines elements of the INEP and UE-ATR). TOH: Typography of harm; Duggan et al, 2014.

[1] The typography of harm is not an outcome measure, rather a guideline for identifying harm.

The effects identified in these measures include: feeling retraumatised and unable to cope (Knox et al., 2011), an increase in unhelpful coping strategies, such as substance use (Berk & Parker, 2009), feeling stigmatised or blamed for not improving (Berk & Parker, 2009),

dependency (Leitner et al., 2013; Lilienfeld, 2007) and interpersonal conflict (Kraus et al., 2011).

Need for consensus

As individual psychological therapy is fundamentally an interaction between therapist and patient, it is essential that representatives from both sides of the interaction collaboratively agree what adverse effects are important. The Delphi method is particularly useful for topics where published literature is inadequate or a topic is poorly defined (Jones & Hunter, 1995). This study poses the research question: what do professionals and experts by experience (that is, people who have undertaken personal therapy) agree should be included on a measure of the adverse effects of psychological therapy? A secondary aim of this study was to compare the perceptions of professionals and experts by experience. This comparison was necessarily exploratory in nature, as there is no previous research in this area.

Method

Study Pre-registration & Ethical Approval

Ethical approval was received from University of Edinburgh's Department of Clinical and Health Psychology Ethics Research Panel. Informed consent was sought before each online survey. Data was collected anonymously and identifying data were deleted. The study protocol was prospectively registered on the Open Science Framework, prior to data collection (https://osf.io/tyxk2/register/565fb3678c5e4a66b5582f67). No changes were made to the study protocol and the analysis was completed as planned. Two additional post hoc analyses were completed and are included in the online Appendices.

Design

A panel of professional therapists and experts by experience were recruited and the Delphi method was applied using the steps described in Yousuf (2007).

Participants & Recruitment

An online, snowball recruitment strategy was used to recruit professional therapists and experts by experience, aiming to include people with experience from across the spectrum of mental health difficulties, and therapeutic styles. A website was created to host the study information and a "sign up" link. This website was promoted via Twitter and email. Professional organisations representing clinical psychologists, psychiatrists, mental health nurses and psychotherapists were approached online, as were a diverse range of UK based charity and advocacy groups asking "Would your followers be interested in this study?". A blog on this topic was published on "The Mental Elf" website which included the study recruitment details.

Recruitment focussed on, but was not restricted to, UK based participants. Completion of the surveys required adequate English language skills and participants were asked to confirm that they were aged 18 years or older and did not have a significant neurological disorder or learning disability. Experts by experience were eligible to take part whether therapy had completed or not. A "both" category was created to account for professionals who also had personal experience of therapy.

Procedure & Analysis

Round 1 of the Delphi process included questions about experience of mental health conditions, therapeutic models, and pertinent demographics deemed relevant to the experience of adverse effects; ethnicity, education and sexual orientation (Crawford et al., 2016). Further demographic information was collected in Round 2. Participants were then invited to answer

four open ended questions about the potential adverse effects of psychological therapy, based upon categories identified in the literature (e.g. Linden, 2013; Parry et al., 2016 etc: see online Appendix A). These questions were first reviewed by a colleague from a mental health charity to ensure clarity and relevance.

Responses were coded by the first author (EMG) using thematic analysis to identify salient themes (Braun & Clarke, 2006). A second coder (JLJ), who was blind to the initial analysis, coded responses from a random sample of 10% of the participants. Themes identified by both coders were compared and divergence was discussed until a final list was agreed. These were re-written as 147 'present tense' statements (included in online Appendix B) for use in Round 2. The Round 2 survey link was emailed simultaneously to the panel and open for three weeks, with one prompt after two weeks. The panel were invited to rate whether each item was important to include on a measure of the adverse effects of psychological therapy using a five-point Likert scale; essential, very important, important, of little importance or not important at all.

Similar to other Delphi studies (Langlands et al., 2008) items rated as essential, very important or important by at least 80% of the each of the two categories were deemed to have reached a high level of consensus and were included in the final outcome measure. Items rated between essential and important by 70-79% of the total panel, or 80% of either group were reassessed in Round 3. All remaining items were excluded from the outcome measure. The Round 2 protocol was repeated in Round 3, and items not meeting the inclusion threshold were dropped. Participants were invited to comment throughout Round 2 and 3 to allow for nuanced opinions and clarification of responses; comments were thematically analysed. An exploratory analysis compared the median rating of each item by professionals and by experts by experience using Wilcoxon rank-sum test using Stata IC- v14.

[Insert Figure 1 here]

Results

Delphi Panel

One hundred and thirty-four people signed up to participate. One hundred and two participants (76% of those recruited) completed Round 1, 62 participants (61% of Round 1 completers) completed Round 2, and 63 (62% of Round 1 completers,) completed Round 3 (see Figure 1 for full details). The professional and both categories were combined and analysed together as professionals. Full demographic details are reported in Tables 2 and 3, and therapy experience details can be found in online Appendix C.

Table 2: Demographic characteristics of Delphi panel- Round 1 information

	Experts by Experience n=51		Professionals n=51	
Ethnicity/Cultural identification	n	%	n	%
White or Euro-American	47	92%	48	94%
Mixed/Multiple ethnic/cultural groups	2	4%	2	4%
Asian/ Asian European or American	1	2%	1	2%
Black/African/Caribbean/Black European	0	0%	0	0%
Prefer not to say	1	2%	0	0%
Work Status				
Employee	30	59%	40	78%
Self-employed	2	4%	4	8%
Student	2	4%	5	10%
Homemaker	2	4%	0	0%
Retired	5	10%	0	0%
Unemployed (able to work)	1	2%	0	0%
Unemployed (unable to work)	7	14%	1	2%
Prefer not to say	2	4%	1	2%
Highest level of education				
Primary school or less	0	0%	0	0%
Secondary/High school completed	4	8%	0	0%
College/University completed	24	47%	9	18%
Post graduate degree	23	45%	42	82%
Sexual Orientation				
Heterosexual	36	71%	44	86%
Lesbian/Gay	1	2%	0	0%

Bisexual/other	7	14%	4	8%
Prefer not to say	3	6%	3	6%
Not sure/Asexual	4	8%	0	0%

Table 3: Demographic characteristics of Delphi panel- Round 2 information

*Data from Survey 2 (n=62)	Experts by Experience n=31*		Professionals n=31*	
Gender*				
Male	0	0%	11	35%
Female	30	94%	20	65%
Prefer not to say/Other	2	6%	0	0%
Age range*				
18-24	2	6%	0	0%
25-34	7	22%	14	45%
35-44	9	28%	12	39%
45-54	5	16%	2	6%
55-64	3	9%	3	10%
65-74	4	13%	0	0%
Prefer not to say	2	6%	0	0%
Country*				
UK	26	81%	29	94%
Other (includes USA, Ireland, Norway, New Zealand)	6	19%	2	6%

Experts by experience reported undertaking therapy for depression (73%), anxiety (37%) and trauma (31%) with a range of therapists, such as clinical psychologists (57%) and/or counsellors (57%). Ten percent of experts by experience did not know their therapist's title/qualification. Almost three-quarters reporting having received counselling (73%) and/or CBT (71%).

Most professionals taking part in Round 1 were applied psychologists (73%). The professionals reported delivering CBT (84%), mindfulness & mindfulness-based cognitive therapy (33%), acceptance commitment therapy (31%) and counselling (24%), for depression (94%), social anxiety (90%), generalised anxiety disorder (86%), trauma (80%) and OCD (80%). Professionals who had personal experience reported receiving counselling (65%), CBT (39%)

and/or psychodynamic or psychoanalytic therapy (39%) for depression (48%), generalised anxiety disorder (26%) and trauma (23%). Nineteen percent of professionals with personal experience reported that this was for personal development.

Most participants reported overall satisfaction with psychological therapy; 57% of experts by experience, 71% of professionals with personal experience and 89% of professionals. Thirty-four percent of experts by experience reported dissatisfaction with therapy received as did 20% of the professionals with personal experience. Only 10% of professionals reported dissatisfaction with providing therapy. More experts by experience were dissatisfied with the amount of information they received about therapy (47%) than were satisfied (43%).

Round 1: Thematic Analysis

Responses to the Round 1 prompts about potential adverse effects of psychological therapy ranged from single words to longer narrative text. Thematic analysis of these responses led to the generation of 147 unique potential adverse effects categorised (reported in online Appendix B) under 9 themes, (detailed in Table 4).

Round 2 and 3: Delphi ratings

Thirty-six items (24%) were rated between important and essential by 80% of both the expert by experience and professional panels in Round 2. Seventy items (48%) were excluded, and 41 items (28%) were included in Round 3 for re-rating (see online Appendix B, and Figure 2). In Round 3, two additional items were rated between important and essential by at least 80% of both categories; 'Increased frequency or intensity of hopelessness or feeling stuck', and 'Own sense of self feels like it's determined by therapist's opinion'. The list, the Edinburgh Adverse effects of Psychological Therapy (EDAPTS – Table 5), was created using 38 items from eight of the nine themes. Some items were expanded to allow for nuanced responses. Twelve extra

items that were rated as important-essential by more than 80% of the expert by experience group, but not by the professional group- were included as supplementary items.

[Insert Figure 2 here]

Table 4: Themes and brief description

Theme	**Description**
Therapy amplifies problem	Potential adverse effects in this theme refer to difficulties that are amplified in therapy, such as acknowledging how serious the problem is, or having painful realisations about one's past.
Increased emotional lability (frequency or intensity)	Participants cited a range of feelings that may be amplified by the therapeutic process; from feeling angry, to feeling exposed or experiencing a 'grief reaction' for the life that could have been lived.
Somatic/physical effects	Similar to 'increased emotional lability', a range of potential physical and/or somatic effects were suggested as related to undergoing psychotherapy; from loss of appetite to headaches to increased stomach aches.
Increased use of negative coping strategies	Participants described using substances or engaging in risky strategies (such as self-harm) to cope with the increased emotional or somatic effects associated with attending therapy.
Sense of self	Engaging in psychotherapy was reported to lead to some changes in how people saw themselves. For some this felt 'determined by the therapist's opinion' or infused with shame or feelings of incompetence if they felt they had been responsible for needing therapy in the first place. Some reported that therapy could 'fragment' their sense of who they were, which then led to the emergence of a different self, who may no longer fit in with their own life.
Therapy process	There were many suggested effects related to the therapeutic process itself, some relating to the power dynamics inherent in the relationship, feeling constrained by the model/therapist's style, and feeling tension with maintaining personal boundaries in therapy.
Practical burden	Psychotherapy requires time and effort, and some of the consequences of this were cited as potential adverse effects; for example, feeling vulnerable between sessions, having less time for 'day to day' life or needing to take time off work.
Impact on relationships	Relationship change was listed by many participants, with many different potential reasons cited. These included; change due to the clients making choices based on new insights, indirect change related to discussions in therapy about past events and change associated with a 'devaluing' of other relationships in comparison to the intimacy of the therapeutic relationship.
Consequences and/or risks	Some potential consequences or risks of engaging with therapy were listed, with some being related to harmful practice (such as risk of abuse by the therapist) and others related to the process. The latter include the risk of

	being misdiagnosed, risk of being perceived negatively if therapy doesn't work and the opportunity cost of not accessing other treatment options instead.

Validity of Concept: Qualitative analysis of comments

Twenty participant comments (17 in Round 2 and 3 in Round 3) raised issue with measuring adverse effects and the rating of items in this study; sample quotes can be found in online Appendix D. Some suggested that the concept of adverse effects of psychological therapy was moot for reasons including that undertaking therapy is necessarily uncomfortable and that the items listed, such as, 'an increase in negative emotions', were integral to the process (4 experts by experience and 2 professionals). Others (3 experts by experience and 2 professionals) stated that some items were indicators of bad therapy – and, as such, did not fit with their concept of adverse effects.

Regarding the rating system; some (1 expert by experience and 2 professionals) reported that rating items as important or not did not capture their nuanced opinion. Eleven participants (5 experts by experience, 3 professionals and 3 with both professional and personal experience) raised concerns about the creation of a list of potential adverse effects, citing "nocebo effects", the likelihood that presenting a list could put people off therapy, and the inclusion of unacceptable outcomes on an outcome measure could suggest that they are 'acceptable' and/or likely outcomes of therapy. Eight (6 experts by experience and 2 both) commented that a list of adverse effects could benefit the therapeutic process by increasing awareness among therapists, prompting pre-emptive discussion of adverse effects or helping to identify "red flags".

Comparison of ratings by Professionals and Experts by Experience

A Wilcoxon rank-sum test compared ratings by experts by experience and professionals (including the 'both' group) for each of the 147 items. In Round 2 there was a statistically significant difference in the ratings for less than 10% of items (n=14) (full details in online Appendix B). Just one item, "Feeling embarrassed about opening up to a stranger" was rated as more important by the professionals than the experts by experience ($Z= -1.98$, $p = 0.05$). All other items rated differently between the groups were rated as more important by the experts by experience.

In Round 3, there was a statistically significant difference for 13 of the 41 items (32%), with all items rated as more important by the experts by experience. Eleven of the 13 items were rated as important by at least 80% of the expert by experience group and were made supplementary items on EDAPTS. One item received a statistically significant different rating by experts by experience and professionals, however did not meet the 80% inclusion threshold; "Therapy failure may lead to a label of "treatment resistant"' ($Z= 2.13$, $p=0.03$).

Post-hoc analyses

There were no male responders in the expert by experience group in Round 2, and a secondary analysis of gender difference in the "both" group was carried out to review whether male (n=7) and female (n=7) responders rated items similarly or differently (see online Appendix E1). This post hoc analysis was underpowered yet indicated there was no differences in rating for 86% of items.

The pre-registered protocol determined analysis based on two categories, professionals and experts by experience, however the proportion of professionals who identified as having both personal and professional experience was larger than anticipated. A Kruskal Wallis test was

used to explore whether analysing the both category as a distinct group would affect the results. (see online Appendix E2). There was less difference across the 3 groups than the pre-specified two group comparison, with the opinions of people in the 'both' category being less conservative than the professional therapist only group, but more conservative than the expert by experience group.

Discussion

The Delphi panel identified most of the adverse effects and process issues included in previously published measures, except for prolongation of treatment and reoffending. Interestingly, the effects common to previous measures were not all rated by the panel as important or essential to be included on an outcome measure; specifically, items relating to deterioration, effects on work/sick leave, sense of failure and stigmatisation. The panel also identified a number of novel items which have not been included in other measures including; feeling under pressure to "use therapy properly", increased self-harm and suicidal ideation, painful realisations, vulnerability, and difficulties with the time limited nature of the therapeutic relationship. The inclusion of the voice of experts by experience is likely to account for these previously unrecognised but important potential adverse effects.

Despite its importance, the opinion of experts by experience is least represented in the literature. Thus, despite not meeting the pre-specified threshold for inclusion, items which were deemed important by the expert by experience group, but not the professionals, were included as supplementary on the EDAPTS (see Table 5). These 12 items include process issues related to power imbalance; such as, "feeling unable to disagree/criticise the process as this will be perceived as denial" and "feeling under pressure to recall bad memories/emotions/give the right answers/improve ". Overall, professionals and experts by experience with experience of face-

to-face therapy appeared to agree in their opinions, although professionals were somewhat more conservative about what to include as adverse effects.

Strengths and limitations

This study represents one of the few attempts to understand the perspective of experts by experience on the adverse effects of psychological therapy. It adhered to a preregistered protocol, thus reducing the risk of researcher bias. There was also a good response rate in Round 3 (62% of the initial sample). In addition, participant opinion was encouraged throughout each survey, which meant participants could critique the study while taking part.

Nonetheless, this study had some limitations. Although the participants were representative of some groups that have been identified as having higher reported adverse effects (Crawford et al., 2016) including adults of working age, people who identify as non-heterosexual and people who are unsure about the type of therapy received; some other groups, including males and people from black and minority ethnic groups, were not well-represented. Similarly, there was little diversity in the professional sample across ethnicity and education levels, however the latter may be a function of the professional requirements to work as a therapist. There was however a wide range of satisfaction with therapy, suggesting that the adverse effects they identified are relevant to people who have had positive and negative experiences of therapy.

The lack of male expert by experience participants in Round 2 was unexpected, however without gender information in Round 1 it is unclear whether this was related to the recruitment strategy, or attrition. Gender differences are complex, however there is some evidence that females are more likely to report and seek intervention for mental health difficulties (McManus et al., 2016; Wilkins et al., 2008) while males are less likely to use mental health services, remain in treatment, or be represented in samples of people with experience of therapy (Ladwig et al., 2014; Wilkins et al., 2008). Preliminary evidence specific to gender difference in the

validation of adverse effects by people with personal experience suggests that there are no significant differences (Parker et al,, 2013).

The inclusion of the 'both' group in the professional category was based on the premise that training and practicing therapy may have a greater impact on opinions of therapy than personal experience, however the impact of personal therapy on professional opinions should not be understated (Wilson et al., 2015). The finding that more than 60% of the initial sample of professionals had personal experience of therapy was also unanticipated. Just 19% of these participants cited receiving therapy for personal development, which is consistent with recent recognition of the high prevalence of mental health difficulties amongst mental health professionals (Tay et al., 2018).

The list of items rated in Rounds 2 and 3 included some ambiguous items, which combined concepts (such as intensity/frequency) or conflated a cause with an adverse effect which may have affected the results. The analysis involved multiple exploratory analyses, all including 147 items; this increases the likelihood of Type II error, and therefore the results must be interpreted with caution. As the Delphi method prioritises the majority opinion, it is possible that minority opinions (either demographic, or therapy specific) may have been overlooked. The diverse sample may affect the internal validity of the final list, however the high rates of agreement across items indicates that a divergent group may be able to agree on this topic.

Implications

Understanding the benefits and risks of particular therapeutic approaches is not only essential for reducing the time and cost incurred by the provision of unhelpful or unsafe interventions, it is also central to informed consent. Informed consent is not only a right (NHS Scotland, 2012) it also enhances collaboration and sets realistic expectations for the therapeutic relationship and reduces the risk of exploitation and harm (NICE, 2011).

This study provides evidence that people on both sides of the therapeutic relationship can agree on what should be included in a definition of adverse effects. Importantly, however, this study found evidence that professionals may be overlooking some adverse effects that are important to people undergoing therapy. Thus, it is recommended that psychological therapists should seek to identify what their clients might perceive to be unwanted effects of therapy, and carefully monitor these as therapy progresses.

The EDAPT list developed here is preliminary. Investigation of the nuances of which effects are necessary, unnecessary and harmful is required, before the clinical validity, reliability of EDAPT list in clinical groups is investigated. Nonetheless, it provides context and a language to discuss the potential adverse effects of therapy, which may inform therapy training and supervision (Castonguay et al., 2010).

The measurement of adverse effects in randomised controlled trials would enable investigation of the mechanisms of change and test whether things do "need to get worse before they get better" across different therapeutic models. Hypothesis driven research of the specific effects of specific therapies is required (Dimidjian & Hollon, 2010), and the results of this study may provide a context within which to generate these questions.

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Table 5: EDAPT: Edinburgh Adverse effects of Psychological Therapy

Therapy amplifies the problem
Painful realisations about own past/childhood/negative experiences/parenting
Being retraumatised
Therapy has highlighted factors that contribute to mental health difficulties, that cannot be changed
No longer being able to avoid painful thoughts/beliefs about oneself
**Viewing own behaviour as abnormal, or as a symptom*
Negative Coping Strategies
Increased self-harm
Increased suicidal ideation
Increased suicide attempts
Developing new ways of coping, but which actually make problems worse, or stop them getting better
**Increased alcohol use*
**Emergence of new 'rules about what I should do' based on what therapist said*
Sense of Self
Own sense of self feels like it is determined by therapist's opinion
**Doubting own thoughts/feelings/responses*
Therapy Process
Feeling over reliant/dependent on therapist
Feeling confused about the process, for example, unsure about how and when it will end
Fear of being left again/abandoned as therapy involves creating a bond that will be severed
Experiencing a sense of loss when the therapist is away or when therapy ends- and having no one to talk to about this loss
The therapy relationship is difficult, which feels like other relationships
**Feeling under pressure to recall bad memories/emotions/give the right answers/improve*
**Feeling unable to disagree/criticise the process as this will be perceived as denial*
**Diagnosis/misdiagnosis can affect own sense of self and may become a self-fulfilling prophecy*
**Feeling vulnerable to negative things therapist says about oneself/one's past/family*
Practical
Therapy requires effort at a time of vulnerability
Feeling vulnerable; in session
Feeling vulnerable; all day after therapy
Feeling vulnerable; between sessions
Relationships
Relationships change as gaining new insight into negative relationships
Relationships change as own behaviour changes, for example, becoming more assertive
Interactions with people are affected if they were discussed in therapy, for example, feeling anger about past events

Increased emotional lability (frequency or intensity)
…anger
…anxiety/fear/panic/ worry
…despair/feeling disheartened/demotivated/helpless/haplessness
…discomfort
…distress
…feeling exposed/vulnerable
…feeling overwhelmed or unable to cope
…guilt/shame
…flashbacks
…seeing or hearing things that might not be there or developing very unusual beliefs that no-one else thinks are true
…being preoccupied with upsetting and intrusive thoughts or having to do certain 'rituals' to feel less anxious
…hopelessness/feeling stuck
…nightmares
…stress
…tired/fatigue/exhaustion/emotionally drained
…feeling upset/sadness/depression
**...bewilderment/confusion*
**...loneliness/aloneness*
**...worthlessness*
Experiencing a grief/loss reaction for life that could have been lived
Anxiety during exposure tasks
Feeling responsible if therapy doesn't help or feeling pressured to 'use therapy properly'
Going into therapy feeling good-then come out feeling low and upset
Worry that the therapy sessions might be unpleasant or that something bad might happen
**Being preoccupied with ideas from therapy*

*Italics; Supplementary items identified as important by 80% of Experts by Experience.

List of Figures

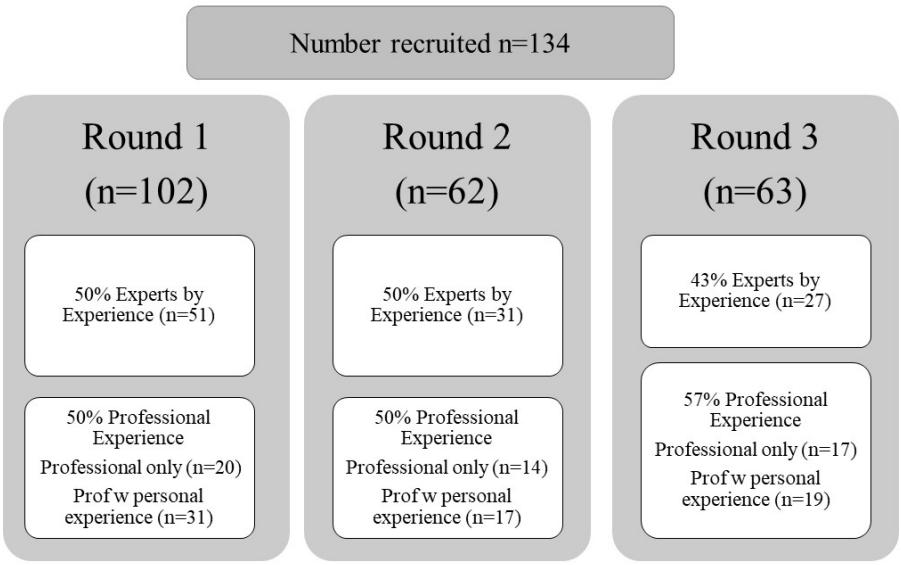

Figure 1: Panel participant numbers per Round

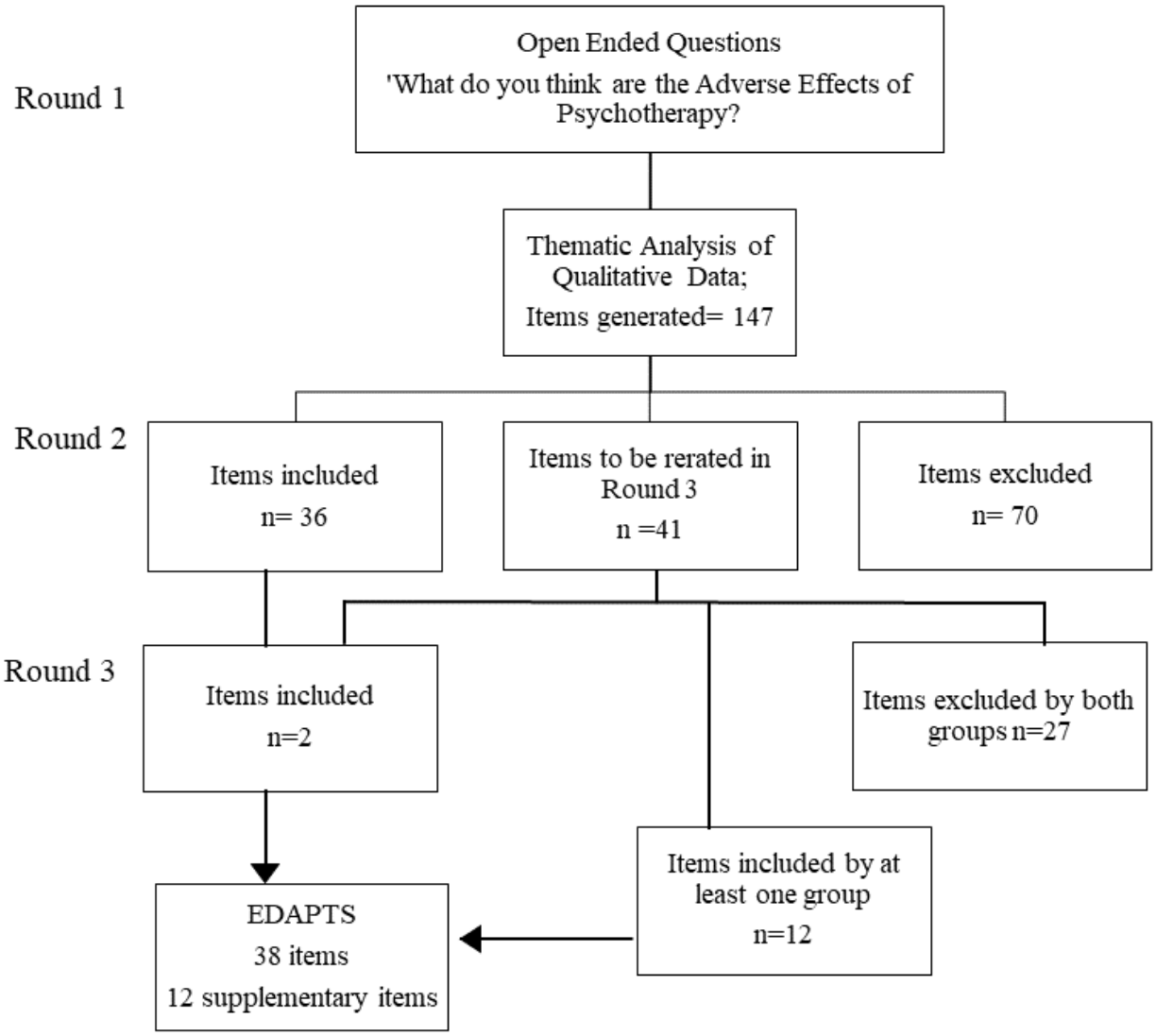

Figure 2; Flow diagram of Delphi rounds