What can therapists learn from a randomised controlled trial? The case of the IMPACT study.

The BACP Research Conference, May 2020

Nick Midgley

Anna Freud
National Centre for
Children and Families

Ch|A|PT|Re
Child Attachment and Psychological Therapies Research
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"I knew that there was no real evidence that anything we had to offer had any effect on tuberculosis, and I was afraid that I shortened the lives of some of my friends by unnecessary intervention."

"I found it impossible to understand. I had considerable freedom of clinical choice of therapy: my trouble was that I did not know which to use and when. I would gladly have sacrificed my freedom for a little knowledge.

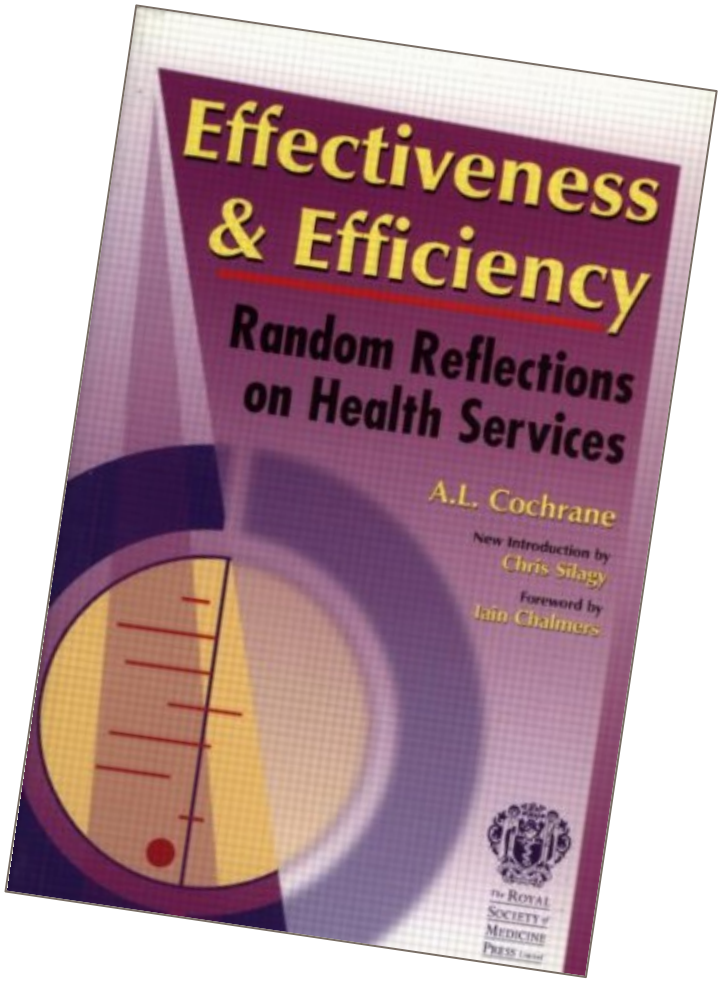
Archie Cochrane and the origins of evidence-based practice

Effectiveness and Efficiency: Random Reflections on Health Services (1972)

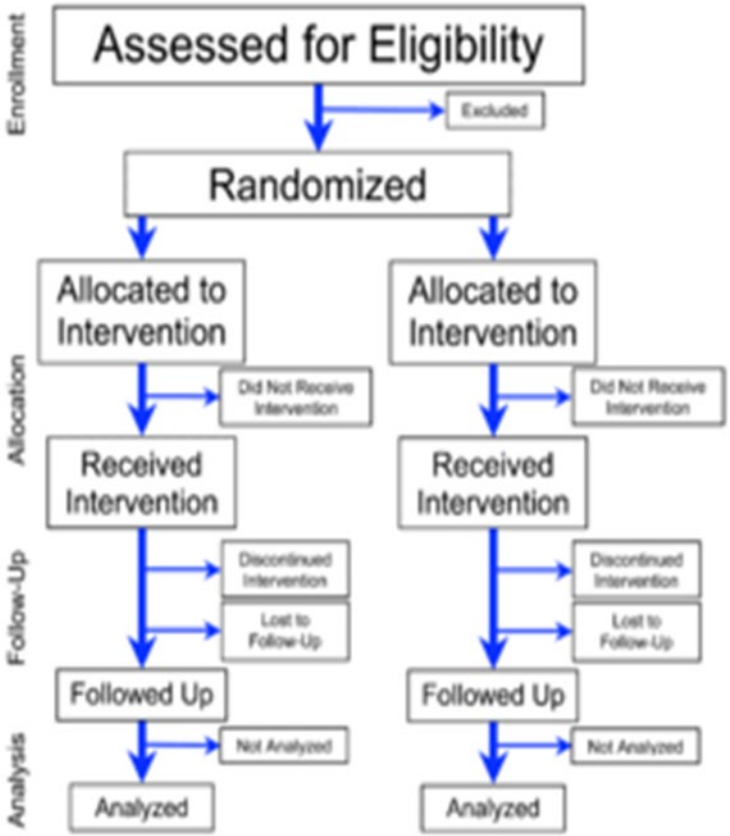
Medicine has not organised its knowledge "in any systematic, reliable and cumulative way".

The need for randomised controlled trials (RCTs)

The rise of 'evidence based practice'



Why the RCT?



With RCTs, different outcomes can be attributed with greater confidence to the impact of the different treatments that are being compared, whilst **minimizing the risk of bias**

'[the] **logic of RCTs is unassailable**; their superiority to observational methods is so self-evident that alternative strategies can be justified only in terms of the limitations of the RCTs' (Fonagy et al., 2003: 17).

And yet…

The RCT design has significant weaknesses when it comes to 'meaningful assessment':

- Over-emphasis on **group statistics** and statistical significance
- Findings from RCTs can be **hard to translate** into the 'real world'
- In focusing on comparisons between **'brand name' therapies**, they often tell us very little about the *mechanisms* by which treatments work

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IMPACT

Improving Mood with Psychoanalytic And Cognitive Therapies

Wirral University Teaching Hospital NHS

NHS Foundation Trust

The Tavistock and Portman NHS

NHS Foundation Trust

Norfolk and Suffolk NHS

NHS Foundation Trust

Anna Freud

National Centre for Children and Families

The aims of the study

IMPACT

Improving Mood with Psychoanalytic And Cognitive Therapies

A comparison of **three psychological therapies** developed for adolescents with moderate/severe depression

465 adolescent patients (11-17 years) randomly assigned to:

- *Cognitive Behavioural Therapy* (CBT, up to 20 sessions); or
- *Short-Term Psychoanalytic Psychotherapy* (STPP, 28 sessions); or
- *Brief Psychosocial Intervention* (up to 12 sessions).

To identify which of these treatments are most clinically- and cost-effective at **maintaining reduced depressive symptoms** 12 months after treatment.

Making IMPACT meaningful…

- Designed as a **'pragmatic' trial**
  - A determination to **maximise our learning**

IMPACT

Improving Mood with
Psychoanalytic And Cognitive Therapies

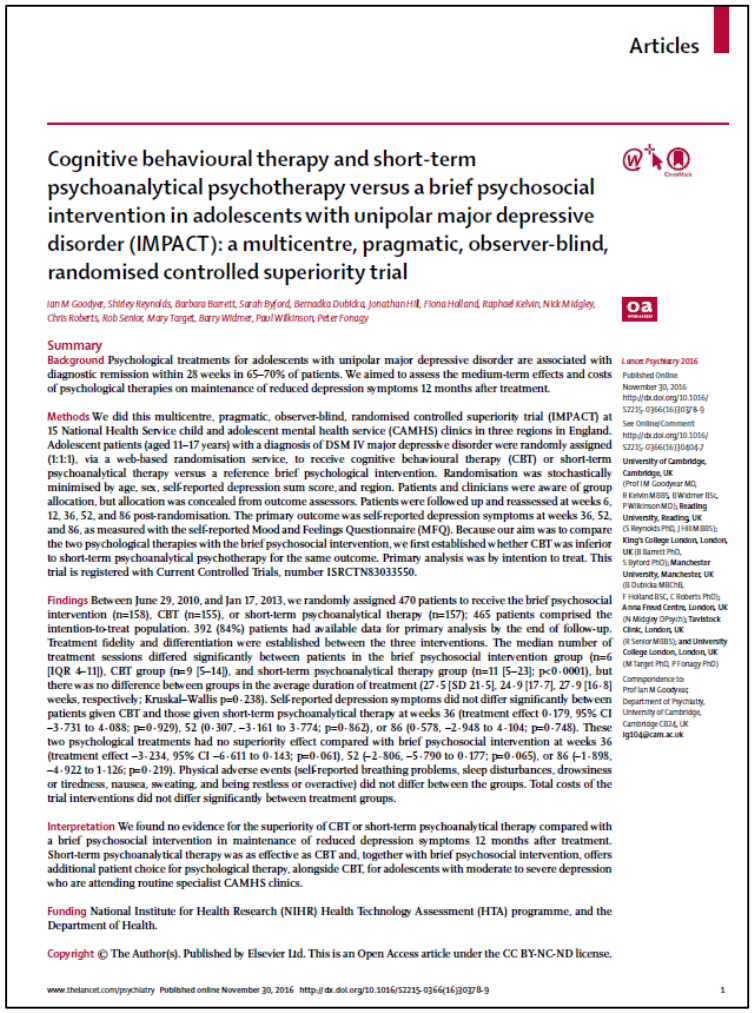
The IMPACT-ME (My Experience) Study

A **qualitative, longitudinal study** involving young people, families and clinicians who are taking part in IMPACT in London

In depth, **semi-structured interviews** with young people, their parents and therapists exploring **expectations and experiences of therapy**

Midgley, N., Ansaldo, F. and Target, M. (2014). 'The meaningful assessment of therapy outcomes: Incorporating a qualitative study into a randomized controlled trial evaluating the treatment of adolescent depression', *Psychotherapy.*

So what were the key findings of IMPACT?



Articles

Cognitive behavioural therapy and short-term psychoanalytical psychotherapy versus a brief psychosocial intervention in adolescents with unipolar major depressive disorder (IMPACT): a multicentre, pragmatic, observer-blind, randomised controlled superiority trial

Ian M Goodyer, Shirley Reynolds, Barbara Barrett, Sarah Byford, Bernadka Dubicka, Jonathan Hill, Fiona Holland, Raphael Kelvin, Nick Midgley, Chris Roberts, Rob Senior, Mary Target, Barry Widmer, Paul Wilkinson, Peter Fonagy

Summary

Background Psychological treatments for adolescents with unipolar major depressive disorder are associated with diagnostic remission within 28 weeks in 65–70% of patients. We aimed to assess the medium-term effects and costs of psychological therapies on maintenance of reduced depression symptoms 12 months after treatment.

Methods We did this multicentre, pragmatic, observer-blind, randomised controlled superiority trial (IMPACT) at 15 National Health Service child and adolescent mental health service (CAMHS) clinics in three regions in England. Adolescent patients (aged 11–17 years) with a diagnosis of DSM IV major depressive disorder were randomly assigned (1:1:1), via a web-based randomisation service, to receive cognitive behavioural therapy (CBT) or short-term psychoanalytical therapy versus a reference brief psychological intervention. Randomisation was stochastically minimised by age, sex, self-reported depression sum score, and region. Patients and clinicians were aware of group allocation, but allocation was concealed from outcome assessors. Patients were followed up and reassessed at weeks 6, 12, 36, 52, and 86 post-randomisation. The primary outcome was self-reported depression symptoms at weeks 36, 52, and 86, as measured with the self-reported Mood and Feelings Questionnaire (MFQ). Because our aim was to compare the two psychological therapies with the brief psychosocial intervention, we first established whether CBT was inferior to short-term psychoanalytical psychotherapy for the same outcome. Primary analysis was by intention to treat. This trial is registered with Current Controlled Trials, number ISRCTN83033550.

Findings Between June 29, 2010, and Jan 17, 2013, we randomly assigned 470 patients to receive the brief psychosocial intervention (n=158), CBT (n=155), or short-term psychoanalytical therapy (n=157); 465 patients comprised the intention-to-treat population. 392 (84%) patients had available data for primary analysis by the end of follow-up. Treatment fidelity and differentiation were established between the three interventions. The median number of treatment sessions differed significantly between patients in the brief psychosocial intervention group (n=6 [IQR 4–11]), CBT group (n=9 [5–14]), and short-term psychoanalytical therapy group (n=11 [5–23]; p<0·0001), but there was no difference between groups in the average duration of treatment (27·5 [SD 21·5], 24·9 [17·7], 27·9 [16·8] weeks, respectively; Kruskal–Wallis p=0·238). Self-reported depression symptoms did not differ significantly between patients given CBT and those given short-term psychoanalytical therapy at weeks 36 (treatment effect 0·179, 95% CI −3·731 to 4·088; p=0·929), 52 (0·307, −3·161 to 3·774; p=0·862), or 86 (0·578, −2·948 to 4·104; p=0·748). These two psychological treatments had no superiority effect compared with brief psychosocial intervention at weeks 36 (treatment effect −3·234, 95% CI −6·611 to 0·143; p=0·061), 52 (−2·806, −5·790 to 0·177; p=0·065), or 86 (−1·898, −4·922 to 1·126; p=0·219). Physical adverse events (self-reported breathing problems, sleep disturbances, drowsiness or tiredness, nausea, sweating, and being restless or overactive) did not differ between the groups. Total costs of the trial interventions did not differ significantly between treatment groups.

Interpretation We found no evidence for the superiority of CBT or short-term psychoanalytical therapy compared with a brief psychosocial intervention in maintenance of reduced depression symptoms 12 months after treatment. Short-term psychoanalytical therapy was as effective as CBT and, together with brief psychosocial intervention, offers additional patient choice for psychological therapy, alongside CBT, for adolescents with moderate to severe depression who are attending routine specialist CAMHS clinics.

Funding National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme, and the Department of Health.

Lancet Psychiatry 2016
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See Online/Comment http://dx.doi.org/10.1016/S2215-0366(16)30404-7

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Cognitive–behavioural therapy and short-term psychoanalytic psychotherapy versus brief psychosocial intervention in adolescents with unipolar major depression (IMPACT): a multicentre, pragmatic, observer-blind, randomised controlled trial

Ian M Goodyer, Shirley Reynolds, Barbara Barrett, Sarah Byford, Bernadka Dubicka, Jonathan Hill, Fiona Holland, Raphael Kelvin, Nick Midgley, Chris Roberts, Rob Senior, Mary Target, Barry Widmer, Paul Wilkinson and Peter Fonagy

DOI 10.3310/hta21120

NHS
National Institute for Health Research

In one slide…

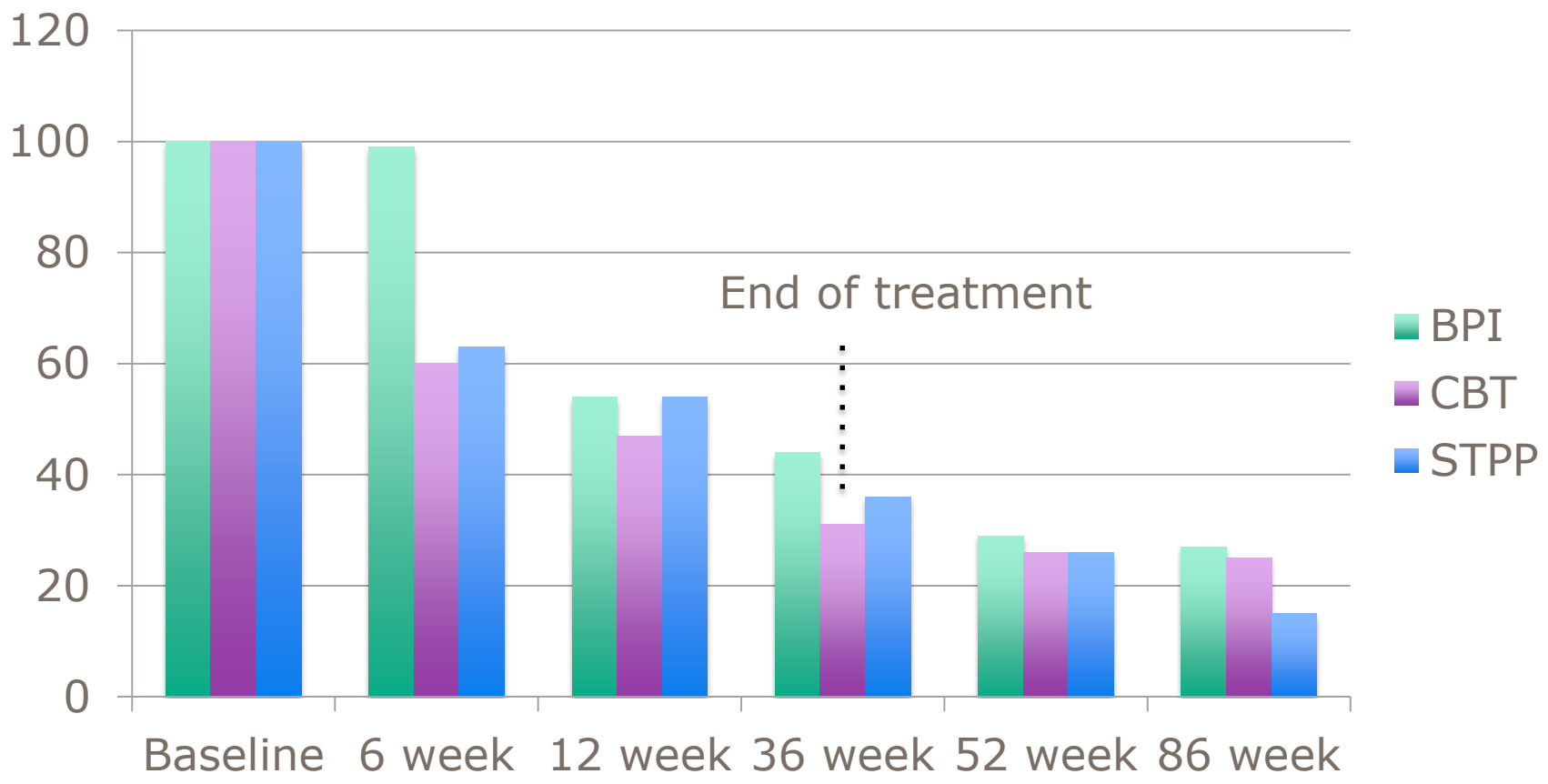
Overall the young people seen in the study showed **major levels of disturbance.**

All three treatments associated with an **average 49–52% reduction in depression symptoms** and **78% in remission** after 86 weeks

There were **no significant differences** between treatments in **clinical- and cost-effectiveness** over the follow-up period.

37% of young people **dropped out** of therapy

Major Depression Diagnosis (K-SADS)



- Sample loss over follow up makes analysis very weak
- 11% in remission at 36 wk but relapsed by 86 wk

NICE Childhood Depression Guidelines (2019)

For 12- to 18-year-olds with moderate to severe depression, offer **individual CBT for at least 3 months**.

If individual CBT would not meet the clinical needs of a 12- to 18-year-old with moderate to severe depression or is unsuitable for their circumstances, **consider the following options:**

- IPT-A (IPT for adolescents)
- Family therapy (attachment-based or systemic)
- Brief psychosocial intervention
- Psychodynamic psychotherapy.

So what might Archie Cochrane say?

- "I would gladly have sacrificed my freedom for a little knowledge"
- Does this study teach us anything about the **process of therapeutic change**?
- What about those who **dropped out or who didn't respond**?

Does this study teach us anything about the mechanisms of therapeutic change?

If outcomes were equivalent, were the therapies all the same?

Midgley, N. et al. (2018). Therapists' Techniques in the Treatment of Adolescent Depression.

Journal of Psychotherapy Integration.

The Comparative Psychotherapy Process Scale

CB sub-scale

Item no.	Item
2	Explicit advice or direct suggestion
3	Therapist initiation of topics and activity
6	Focus on irrational/illogical belief system
9	Specific outside of session activity or task
11	Explain rationale, technique, or treatment
12	Focus primarily on current life situations
15	Provide information symp, disorder, or tx
17	Practice behaviors between sessions
18	Teach specific techniques to patient
20	Interacts in teacher-like (didactic) manner
	CPPS CB subscale

PI sub-scale

Item no.	Item
1	Explore uncomfortable feelings
4	Feelings & percepts linked to past exp.
5	Similar relationships over time
7	Focus on patient–therapist relationship
8	Experience and expression of feelings
10	Address avoid topics & shift in mood
13	Alternative understanding of experiences
14	Recurrent patterns of action/feel/exp.
16	Patient initiates discussion
19	Explore wish, fantasy, dream, EM
	CPPS PI subscale

Hilsenroth et al., Comparative Psychotherapy Process Scale (CPPS)

So are therapies all the same?

STPP, CBT and BPI **could be clearly differentiated,** but certain items **common to all three**:

- Client-led, a focus on emotions, & helping the client to see things in a different way

Psychodynamic therapy puts emphasis on *exploring the therapy relationship, patterns of relating & uncomfortable feelings*

In CBT the therapist *gives more advice, sets tasks, and is more explicit in explaining what they are doing*

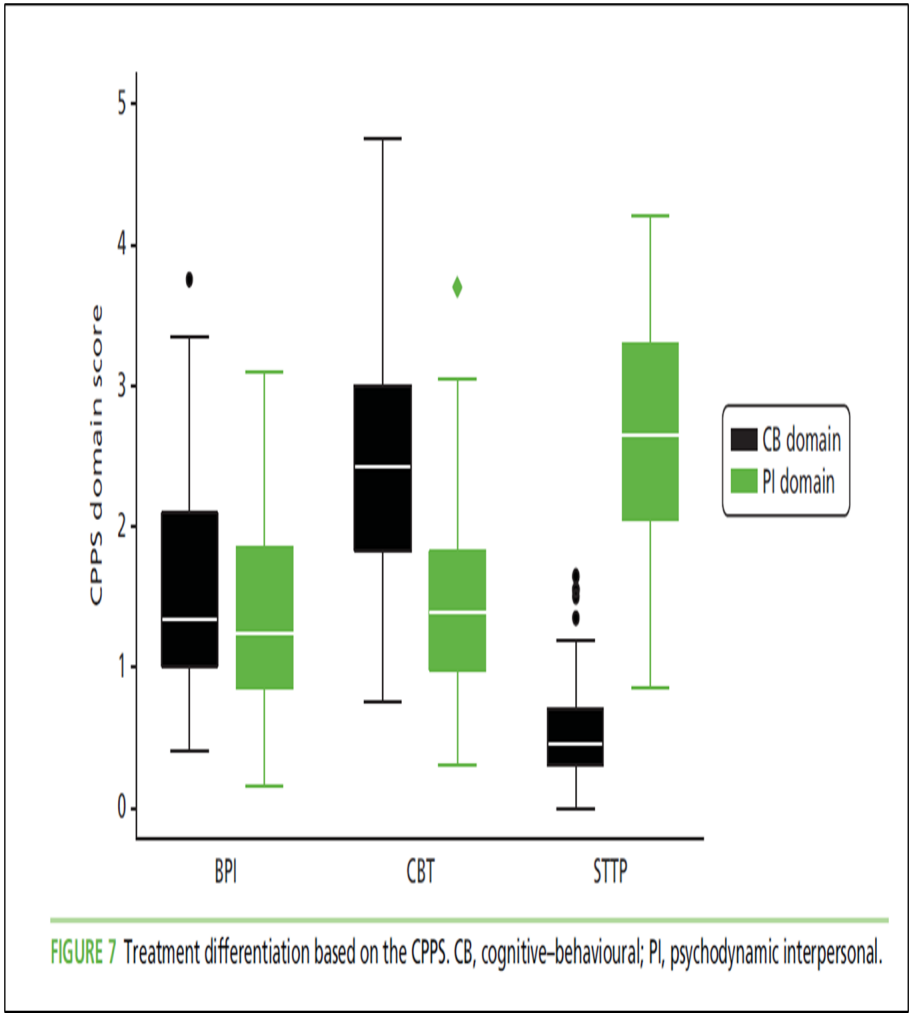


FIGURE 7 Treatment differentiation based on the CPPS. CB, cognitive–behavioural; PI, psychodynamic interpersonal.

What about when we look at things from the young person's perspective?

Article

Clinical Child Psychology and Psychiatry
1–13
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Adolescents' experiences of brief psychosocial intervention for depression: An interpretative phenomenological analysis of good-outcome cases

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Psychology and Psychotherapy: Theory, Research and Practice (2019)

The British Psychological Society
www.wileyonlinelibrary.com

The therapeutic relationship in Cognitive Behaviour Therapy with depressed adolescents: A qualitative study of good-outcome cases

Eva Wilmots[1]*, Nick Midgley[2], Lisa Thackeray[1], Shirley Reynolds[3] and Maria Loades[4]

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Clinical Language Sciences,

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2019, VOL. 45, NO. 2, 209–228
https://doi.org/10.1080/0075417X.2019.1659387

Routledge
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Short-term psychoanalytic psychotherapy with a depressed adolescent with borderline personality disorder: an empirical, single case study

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[a]Child Attachment and Psychological Therapies Research Unit (ChAPTRe), Anna Freud National Centre for Children and Families, and University College London, London, UK; [b]School of Health Sciences, City, University of London, London, UK; [c]Department of Psychosocial Studies, Birkbeck College, University of London, London, UK

Aims and design of the study

To explore **experiences of the therapeutic relationship** for adolescents in the context of **good outcome CBT.**

The participants were **five female participants aged 14-18 years**

Participants took part in a **semi-structured interview** as part of the IMPACT-ME study at the end of therapy. They were analysed using **Interpretative Phenomenological Analysis**

Table 1. Participant and therapist demographics

Participant	Age at referral	Age at time of interview	Sessions attended	MFQ Score Time1	MFQ Score Time2	Therapist gender
Maddison	13.49	14.34	21	25	8	Female
Jade	17.08	17.90	20	64	26	Female
Harper	17.28	18.37	8	60	18	Female
Sarah	15.53	16.42	10	45	23	Male
Laura	16.25	17.18	19	42	5	Female

"Something that you can't really get anywhere else": Feeling Accepted and Understood

Young people valued therapists' personal qualities such as warmth, and sensitivity, and being accepting of their experiences.

They felt safe and supported as a result, which was facilitative of a positive therapeutic relationship.

> At the time I felt I had no support. It was important that I went somewhere where someone would listen to me and think that I was significant (Harper, 17)

"She gave me the seeds, and I grew a beautiful plant": Facilitating Change

Young people valued therapists who were experienced in helping others from a psychological perspective

Therapist's didn't take over, but played the role of a facilitator, providing the tools for the young people to enact change in their lives.

It helps you see how you were like behaving and [how] thoughts are linked to how you feel … and how if you change one it changes all the others (Laura, 16).

"She wanted to know what I wanted to get from it": the importance of shared-decision making

Experiencing a therapist who was collaborative, inquisitive, and valued their thoughts and opinions, left young people feeling included in the decision-making around their care

> Every session she asks me like what was helpful and what was not helpful (…) So I think she's very like, open to like criticism and open to like improving things so that it's easier for me (…) (Jade, 17)

What about those who dropped out or who didn't respond?

Sally O'Keeffe, PhD student at UCL

The aims of this research

To improve our understanding, in relation to depressed adolescents, of:

- **who** is most likely to drop out of therapy,

- **what** impact this may have on clinical outcomes

- **why** they may drop out,

- and offer some indications of **how** this may be addressed clinically

Psychotherapy Research, 2018
Vol. 28, No. 5, 708–721, https://doi.org/10.1080/10503307.2017.1393576

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PREMATURE TERMINATION

Predicting dropout in adolescents receiving therapy for depression

SALLY O'KEEFFE[1,2], PETER MARTIN[2,3], IAN M. GOODYER[4], PAUL WILKINSON[4], IMPACT CONSORTIUM[4†], & NICK MIDGLEY [1,2]

…ology, University College London, London, UK; [2]Child …Re), Anna Freud National Centre for Children and Families, …ty College London, London, UK & [4]Department of

NEW RESEARCH

Prognostic Implications for Adolescents With Depression Who Drop Out of Psychological Treatment During a Randomized Controlled Trial

Sally O'Keeffe, PhD, Peter Martin, PhD, Ian M Goodyer, MD, Raphael Kelvin, MRCPsych, Bernadka Dubicka, MD, IMPACT Consortium, Nick Midgley, PhD

Objective: High therapy dropout rates among adolescents have been reported, but lit… outcomes. This study aimed to examine clinical outcomes in adolescents with depression … whether this varied by treatment type.

Method: Data were drawn from the Improving Mood with Psychoanalytic and Cognitiv… comparing a brief psychosocial intervention, cognitive-behavioral therapy, and short-term … major depression. The sample comprised 406 adolescents with a diagnosis of major dep… planned end of therapy. Primary outcome was self-report Mood and Feelings Questionna… Outcome Scale for Children and Adolescents, Revised Children's Manifest Anxiety S… diagnosis.

Results: During follow-up, there was a nonsignificant trend for dropouts to report highe… showed insufficient evidence for an association between dropout and outcomes.

Conclusion: In contrast to studies of adult therapy, there was no strong evidence tha… outcomes compared with those who completed therapy, when dropout was defined as … challenges us to understand why adolescents stop going to therapy, how dropout should … needed.

Clinical trial registration information: Improving Mood and Preventing Relapse … Therapy; http://www.isrctn.com/; 83033550.

Key words: outcome, dropout, psychotherapy, depression, adolescence

J Am Acad Child Adolesc Psychiatry 2019;■(■):■–■.

frontiers in Psychology

ORIGINAL RESEARCH
published: 05 February 2019
doi: 10.3389/fpsyg.2019.00075

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'I Just Stopped Going': A Mixed Methods Investigation Into Types of Therapy Dropout in Adolescents With Depression

Sally O'Keeffe[1,2], Peter Martin[2,3], Mary Target[1] and Nick Midgley[1,2]*

[1] Research Department of Clinical, Educational and Health Psychology, University College London, London, United Kingdom, [2] Child Attachment and Psychological Therapies Research Unit, Anna Freud National Centre for Children and Families, London, United Kingdom, [3] Department of Applied Health Research, University College London, London, United Kingdom

Anna Freud
National Centre for
Children and Families

Key findings of these studies

- **37%** of young people dropped out of therapy
- **Few pre-treatment predictors of dropout** were found
- Those who stopped coming to therapy did **not necessarily have poorer outcomes…**
- Different sub-groups of dropouts could be identified: 'got what I needed', 'troubled' and 'dissatisfied'

The 'dissatisfied' dropouts

The 'dissatisfied' dropout reported stopping therapy because they **did not find therapy helpful.**

They were **critical of the therapy** they received and described a range of things about the therapy they did not like.

The therapists of the 'dissatisfied' dropout tended **not to indicate awareness of the adolescents' criticisms** of the therapy.

Example of the 'dissatisfied' dropout: Fiona (13, STPP)

She just sat there and hummed for an hour at everything that I said. I hated it. She made me really angry because it just felt like I was talking to a brick wall. I didn't even want to talk to her because she didn't engage with me at all. It was just completely pointless.

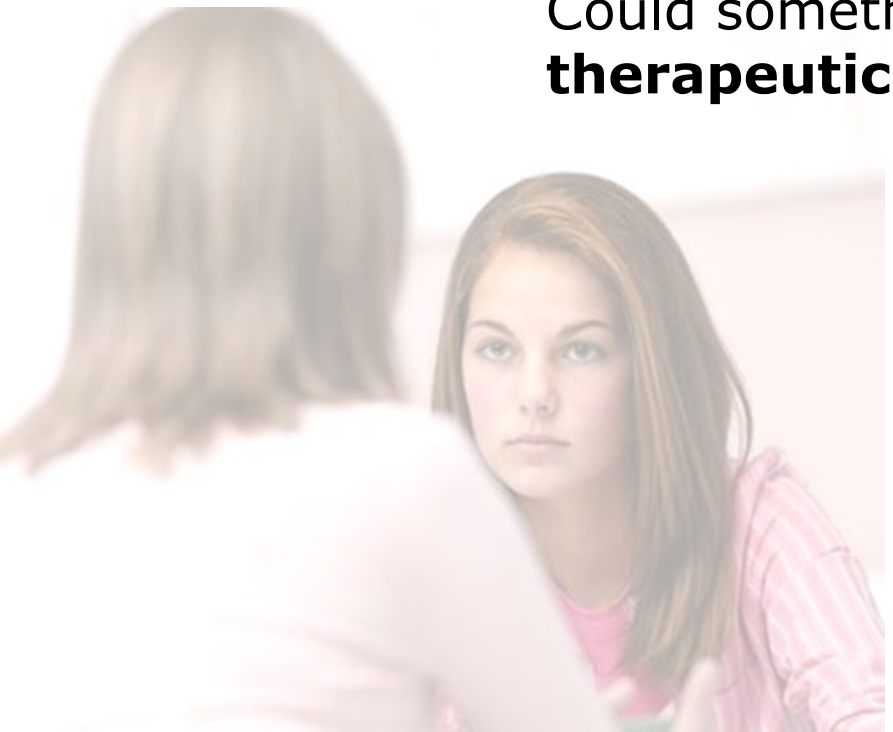
Well I wasn't enjoying it, well not enjoying it because it's not something you're going to have fun in doing, but I wasn't benefiting from it and it just seemed really pointless because I didn't feel like I was getting anything out of it.

I think the sessions sort of stirred stuff up and the fear was that she'd feel worse again.

What is important about 'dissatisfied' dropouts?

Compared to those who completed therapy or who dropped out because they 'got what they needed', the **'dissatisfied' dropouts ended up with poorer outcomes.**

Could something be **going wrong with therapeutic alliance**?



What is meant by the 'therapeutic alliance'?

A multidimensional construct, comprising:

1) the agreement on the **tasks and goals** for treatment between a client and therapist, in the context of an **emotional bond** (Bordin, 1979).

2) An **ongoing process of negotiation** between the client and therapist, consisting of ruptures and resolution (Safran & Muran, 1996):

- **Withdrawal ruptures** and **confrontation ruptures**

An investigation into patterns of rupture-resolution in the lead up therapy drop-out

Aim: To investigate the role of the therapeutic alliance and rupture-repair processes in the lead up to:

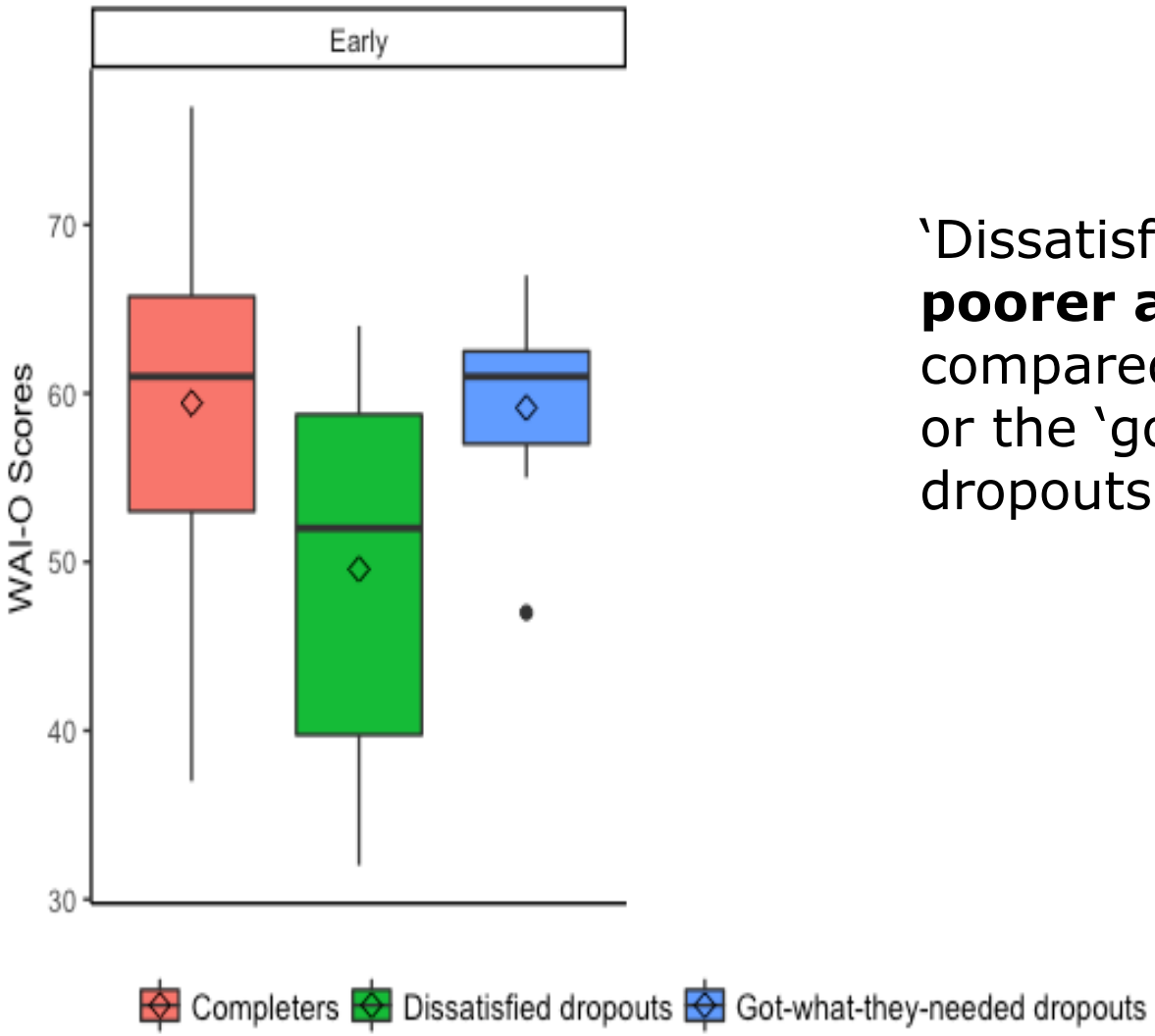
- Treatment completion (n = 14); 'Dissatisfied' dropout (n = 14); 'Got-what-they-needed' dropout (n = 7).

Data: Audio recordings of therapy sessions. An early and late session for each case was selected.

Measures:

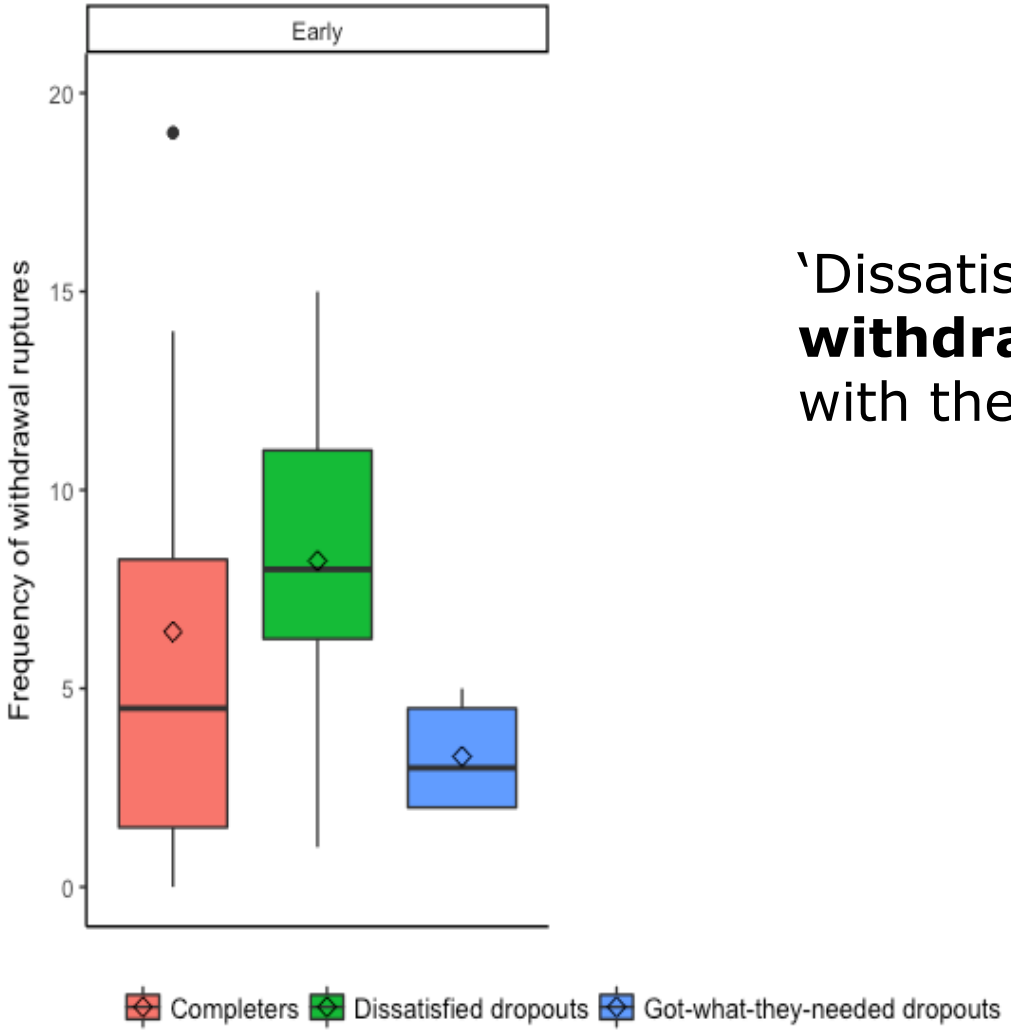
- Working Alliance Inventory – Observer (WAI-O; Tracey & Kokotovic, 1989)
- Rupture Resolution Rating System (3RS; Eubanks et al., 2015)

Therapeutic alliance scores



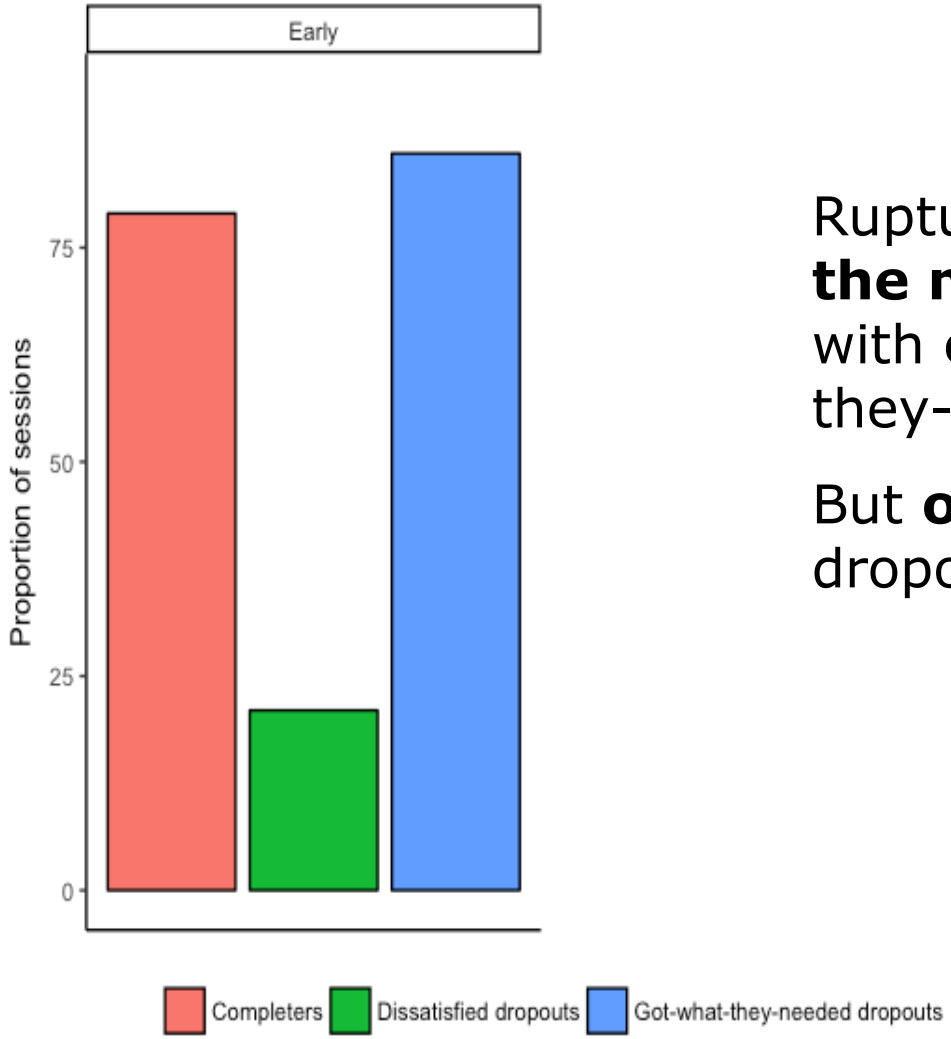
'Dissatisfied' dropouts had **poorer alliance scores** compared with the completers or the 'got what I needed' dropouts.

Withdrawal rupture frequency



'Dissatisfied' dropouts had **more withdrawal ruptures** compared with the other groups.

Resolution of ruptures



Ruptures rated as **resolved for the majority (86%) of sessions** with completers and 'got-what-they-needed' dropouts,

But **only 21% of 'dissatisfied'** dropout ruptures were resolved.

How do therapists contribute to rupture resolution and non-resolution?

Non-resolution, therapists contributed via:

- Minimal response
- Persisting with a rejected therapeutic activity

Rupture resolution, therapists contributed via:

- Re-directing the client
- Providing rationale for their approach
- Clarifying misunderstandings

Implications for clinical practice

Dropping out of therapy may **not be a 'bad' thing in itself** – some adolescents may have more of a 'drop in' approach?

'Dissatisfied' dropout is associated with poorer outcomes, and there may be **indications quite early in therapy** of subsequent dis-engagement.

On way to address this may be through greater attention to repairing **therapeutic alliance ruptures**

Some final comments

What can practitioners learn from the IMPACT study?

- Something about the **effectiveness of talking therapies** for severely depressed adolescents?
- Something about the **mechanisms of therapeutic change**
- Something about those who **dropped out,** why it matters and what may contribute to it.

The IMPACT study has given us the opportunity to explore many interesting clinical questions…

- Young peoples' **expectations of therapy** (Midgley et al., 2015)
- Adolescents' views and experiences of **SSRI antidepressants** (Maroun et al., 2017)
- What is a **'good outcome'?** (Krause et al., in press)
- **Trajectories of change** in therapy (Davies et al., 2019)
- **Changes in neural functioning** following CBT (Chattopadhyay, 2017)
- Can **therapists predict** who responds to treatment? (Nakajima, in prep)
- The **experience of being the parent** of a child with depression (Stapley, 2017)
- Therapist/client **interaction structures** in CBT and STPP (Calderon et al., 2018)
- The **meaning of silence** in therapy (Acheson et al., in prep)
- How young people **respond to interpretations** around endings (della Rosa & Midgley, 2017)

Last thoughts: Cochrane re-visited

Cochrane wanted to avoid the mistakes he'd made, and try to base our practice on knowledge

RCTs do play a part in helping us to understand 'what works for whom'

But **no form of evidence** provides certainty…

Beyond the 'hierarchy of evidence', we need to promote a **pluralistic research culture:** valuing multiple perspectives, and accepting uncertainty

Thank you!

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