Exploring Clinicians’ Experiences of Delivering Family Based Treatment and the Factors They Think Contribute to Dropout and Remaining in Treatment

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Introduction

Background

Approximately 1.25 million people in the United Kingdom (UK) have an eating disorder (Beat, 2019). Eating disorders (ED) have devastating effects such as medical complications, psychological distress and mortality as a result of physical health problems or suicide. There are several types of ED; those recognised in the fifth edition of the Diagnostic and Statistical Manual (DSM-5) include: Anorexia Nervosa (AN), Bulimia Nervosa (BN), Binge-Eating Disorder, other specified feeding or ED and unspecified feeding or ED (APA, 2013).

AN is characterised by an intense fear of gaining weight or becoming fat, subsequently restricting energy intake or compensating for intake. Therefore, individuals with AN have a significantly low weight for their age, sex and height, accompanied by a distorted image of their body (APA, 2013). AN commonly develops in adolescence, although prevalence in this population is unknown (Beat, 2019). Symptoms are recognised in children as young as 8 and can severely disturb physical, emotional and social development (Le Grange et al., 1992). Therefore, The National Institute for Health and Care and Excellence (2018) emphasise the need for early detection and effective treatment in children and young people (CYP), as this improves recovery rates, lowers the risk of relapse or hospitalisation and reduces the likelihood AN continuing into adulthood.

It is well established that family problems, such as blurring of role boundaries and avoidance of conflict, contribute to the development and maintenance of EDs (Morgan & Russel, 1975). Therefore, NICE guidelines recommend family therapy (FT) as one of the primary treatments for CYP with AN (NICE, 2017). FT can be delivered to single families or is sometimes offered with other families (multi-FT).

Service Context

The Leeds Children and Young People’s Eating Disorder Service (CYP-EDS) was formed in November 2016 to support CYP up to age 18 who have a diagnosis of an ED.
The service utilises a multi-disciplinary team of dieticians, clinical psychologists, psychiatrists, occupational therapists and Child and Adolescent Mental Health Service (CAMHS) practitioners who provide assessment and intervention. Consistent with national guidelines, assessments for non-urgent referrals take place within four weeks, urgent within one week and emergency within 24-hours. Assessment takes 3-4 hours then the CYP receives a diagnosis and treatment recommendations.

When the service formed (as a result of merging three ED teams in Leeds), a couple of staff members were already trained in multi-FT. However, the service decided not to pursue this model of delivery as they were aware of some of the difficulties other services had experienced in trying to implement it. Some of these difficulties were that practicalities made it difficult for families to attend together and trying to co-ordinate this made this approach labour intensive for clinicians. The service also already had two trained family therapists working with single families. This approach fit better with the service model and NICE recommendations, therefore, all clinicians in the CYP-EDS were trained in Family Based Treatment (FBT). Three clinicians have become accredited, the rest are working towards this and are receiving supervision from the Training Institute for Child and Adolescent Eating Disorders in America.

FBT was outlined by Lock and Le Grange (2001). It is a manualised treatment consisting of three phases over approximately 20 sessions (see table 1).

**Table 1: Overview of FBT.**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Overview</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (Sessions 1-10)</td>
<td>Parents take full control in establishing a normal eating pattern and restoring weight in the CYP. One session includes a family meal where the clinician observes interactions and offers suggestions.</td>
</tr>
<tr>
<td>2 (Sessions 11-16)</td>
<td>Gradually handing back control over eating to the CYP once weight restoration has been achieved.</td>
</tr>
<tr>
<td>3 (Sessions 17-20)</td>
<td>Establishing healthy independence. Focuses on increasing autonomy in the CYP, re-establishing family relationships/roles and issues relating to adolescence.</td>
</tr>
</tbody>
</table>
Literature Review

A few studies have evaluated FBT and reported that it is effective for CYP with AN (Agras et al., 2014; Paulson-Karlsson, Engstrom & Nevonen, 2008). Lock et al., (2005) was the first to evaluate the manualised version of FBT utilised by the CYP-EDS. FBT was demonstrated to be effective as 60% of CYP achieved a significant change in weight for height (>95%) and a ‘normal’ score on the Eating Disorder Examination Questionnaire. Furthermore, 90% no longer met the DSM-IV criteria for AN in relation to their weight. Whilst these results seem promising, a Cochrane review concluded that there is minimal evidence suggesting that FT is more effective than supportive therapy and highlighted that bias/selective reporting regarding what constitutes effective treatment plagues much of the literature, especially when researchers evaluate their own treatments (Fisher et al., 2019).

Some studies have built upon research suggesting that FBT is effective by exploring which components of FBT contribute to its effectiveness. Ellison et al., (2012) found that the core features of parental control, externalising AN and family cohesiveness predicted greater weight gain and encouraged families to remain in treatment (RIT). Furthermore, Dimitropoulos et al., (2017) explored clinicians’ views regarding what is most important for FBT to be effective and concluded that parental empowerment was key. Additionally, weight gain before session four (Doyle et al., 2010; Madden et al., 2015) and mothers with fewer depressive symptoms (Forsberg et al., 2017) predict greater improvement in weight and ED symptoms at end of treatment.

Other studies have explored factors that contribute to dropout or remaining in FBT. Low parental control, poor alliance between mother and therapist, parental perception that treatment was not effective, a desire/need for different treatment and participant refusal have been found to predict dropout (Ellison et al., 2012; Lock et al., 2005). However, Ellison et al (2012) demonstrated that age and illness severity pre-treatment were not significantly related to dropout. Blow, Sprenkle and Davis (2007) suggested that therapist enthusiasm and belief in treatment are more likely to facilitate therapeutic change and subsequently encourage persistence with treatment.
Whilst it is helpful that these studies investigate factors that contribute to RIT and dropout, they possess some limitations. First, they rely on outcome measures to assess factors that may predict dropout and outcome measures can over-simplify complex issues and prevent deeper exploration/understanding (Carr, 1994). Second, studies use different definitions of dropout i.e. completing 80% of sessions vs discontinuing treatment altogether, which contributes to varying results and conclusions. Finally, the above studies were carried out in different service contexts so lack generalisability to the Leeds CYP-EDS who wish to understand the reasons why their families drop out or RIT.

Present study

This service evaluation project (SEP) was commissioned by Dr Julie Franklin (Consultant Clinical Psychologist) and aimed to explore the initial implementation of FBT in the service. The study was conducted in two parts. The first part utilised quantitative data to investigate the effectiveness of FBT. The second part (this study) is outlined below. Both parts were conducted with a view to make recommendations to the CYP-EDS and influence and inform ongoing implementation and utilization of FBT.

Aims

- Provide staff with the opportunity to reflect upon their experiences of implementing and delivering FBT.
- Establish factors clinicians think contribute to dropout (defined in this study as discontinuing FBT early/before treatment completion).
- Highlight factors clinicians think increases the likelihood of families remaining in FBT.

Method

Design

The study was exploratory as FBT was a new intervention implemented by the service. Therefore, one-to-one semi-structured interviews were selected as the most appropriate method of data collection, as they explore topics and investigate research questions in
depth, whilst providing flexibility (Rubin & Rubin, 2012). An alternative method considered was a focus group, however, after discussion with the commissioner, it was agreed that the shared nature of a focus group could be a barrier to some clinicians providing their opinions, in that they may just agree with the prevailing opinion.

The design intended to compliment study one. One limitation of study one was that there was little information surrounding why service-users dropped out. Hence, one of the main aims of this study was to investigate what clinicians think contributes to dropout. An alternative design considered was to interview service-users, however, as those who dropped out were of interest, there were concerns surrounding whether enough service-users would be recruited within the timescale of the study and whether it would be ethical to approach them depending on the circumstances surrounding dropout.

Participants

All clinicians who had delivered FBT within the service prior to 31st December 2018 were invited to take part. All seven (6 female, 1 male) consented to partake. Clinical roles included consultant clinical psychologist, consultant psychiatrist, occupational therapist and CAMHS practitioners. No further participant details will be reported in order to maintain anonymity.

Recruitment

Clinicians were aware of the SEP and had expressed interest in taking part prior to recruitment, therefore, problems with recruitment were not expected. Despite clinicians’ informal interest in being interviewed, the process of gaining informed consent outlined in the ethics application was followed (appendix 1). Clinicians were made aware of the aims of the SEP in a team meeting before the information sheet (appendix 2) and consent form (appendix 3) were emailed to them. They were then encouraged to arrange an interview with the researcher via email.
Procedure and Materials

Interviews were held between March and April 2019. Participants were offered the opportunity to re-read the information sheet and ask questions before signing the consent form. Participants took part in a semi-structured interview which lasted 45-60 minutes (see appendix 4 for interview schedule). After consultation with the researcher’s academic tutor, it was agreed that writing word-for-word responses was an adequate method of recording the interview content and would free-up more time for the thematic analysis so that the initial themes could be presented to the team in a timely manner.

Data Analysis

Interviews were analysed using thematic analysis (see table 2 for overview). This method involves examining the whole dataset to acquire repeating patterns of meaning (themes) and was chosen because it describes the data in rich detail (Braun & Clarke, 2006). Each of the three main interview questions were analysed and are reported separately as it was agreed, after consultation with the commissioner and the researcher’s academic tutor, that this would be more helpful to the service.

The thematic analysis was inductive as it was data-driven rather than based on theoretical interest or a pre-existing coding framework. Other methods such as interpretative phenomenological analysis and grounded theory were disregarded as they seek patterns in data to generate a theory (Braun & Clarke, 2006) which was not an aim.

Table 2: Steps in the thematic analysis.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Overview of process</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Familiarising yourself with the data</td>
<td>Read all interviews twice and noted down key ideas.</td>
</tr>
<tr>
<td>2. Generating Initial Codes</td>
<td>Coded units of meaning by writing in margins of transcripts. Typed codes into a Microsoft word document</td>
</tr>
<tr>
<td>3. Searching for themes</td>
<td>Clustered codes to create initial themes in Microsoft word. Considered the relationship between codes and themes by putting the codes into text boxes and moving them around.</td>
</tr>
</tbody>
</table>
4. Reviewing themes

Sent themes to commissioner to check for face validity. Read all the data extracts in relation to each theme to ensure the data supported the theme and revised where necessary. Re-read entire dataset to ensure that all data that falls within themes had been captured. Added anything that had been missed.

5. Defining and naming themes

Presented theme ideas to the service and gained feedback. Refined themes. Generated theme names to capture the essence of the theme.

6. Producing the report

Selected extracts to include in the report to enable the research questions to be answered.

Credibility check

As suggested by Elliott, Fischer and Rennie (1999), steps were taken to ensure that themes generated are credible. Initial codes and themes were discussed with the commissioner to assess face validity before the themes were reviewed. After themes had been reviewed, they were presented to the service including the clinicians who had been interviewed. The team were encouraged to comment on themes and make suggestions regarding changes they would make. Clinicians agreed that the themes supported their experiences.

Ethics

Ethical approval was provided by the University of Leeds School of Medicine Research and Ethics committee in January 2019 (Ref: DClinREC18-011). For full ethical considerations see the study’s research ethics application (appendix 1).

Results

What are clinicians’ experiences of delivering FBT within the service?

This question generated two themes and nine subthemes outlined below (See table 3 for evidence).
Theme 1: Positive Experiences

Most clinicians reported that overall, they had a positive experience of delivering FBT. This theme consisted of four subthemes: ‘structure is containing’, ‘empowers families’, ‘value of supervision’ and ‘increased confidence over time’.

Structure is containing
The three treatment phases used to structure FBT helped clinicians to feel contained in delivering it, which was helpful as they were learning a new approach. They suggested that the reason for this was that the three phases were broken down into sessions which provided structure and made FBT simpler to deliver.

Empowers families
The key feature of FBT which encourages and supports families to be empowered made clinicians feel good and was a positive experience for them, especially as many parents attend initial appointments feeling helpless and disempowered by AN. Clinicians thought that supporting the parents to understand that they themselves are the experts in knowing what their CYP needs to weight restore was empowering because it reduced the family’s dependence on the therapist.

Value of supervision
Group supervision contributed to clinicians’ positive experience of implementing FBT. They reported that the facilitators are very experienced and passionate about FBT, which increased their own enthusiasm and helped them feel supported. Clinicians also talked about the value of supervision in helping them to further their learning, for example, how to know when to move between the different phases of FBT. They thought that sharing their experiences with colleagues at different stages of training helped them to learn more.

Increased confidence over time
Clinicians were pleased that their confidence in delivering FBT increased over time. They attributed this to experience/practice and to the learning in supervision groups.
Theme 2: Challenges

Clinicians expressed that despite their positive experiences, they encountered some challenges in implementing FBT. This theme consisted of five subthemes: ‘fidelity is difficult’, ‘complexity of service-users’, ‘access to resources’, ‘facilities’ and ‘confusion regarding additional support’.

Fidelity is difficult

Clinicians were unanimous in the opinion that one of the challenges of delivering FBT is that it is difficult to do so without drawing upon other models of therapy they have utilised previously. Clinicians highlighted two reasons fidelity was difficult. First, FBT was different to their previous style of working where they had found it useful to integrate approaches, especially with more complex service-users. Therefore, this subtheme overlaps with the subtheme ‘complexity of service users (no one fit for all)’. The second reason clinicians found fidelity difficult was because they felt the manual contains less advice for when sessions were not going to plan or were more challenging, so they were tempted to draw upon other approaches to help. However, despite finding maintaining fidelity to FBT challenging, all clinicians reported efforts to do so, for example by re-reading parts of the manual to remind them of session objectives or discussing challenges in supervision.

Complexity of service users (no one fit for all)

Another challenge was that clinicians felt their service-users were more complex than those who FBT was developed for i.e. service-users whose main difficulty was AN. However, clinicians reported that their service-users had many co-morbidities such as self-harm or post-traumatic stress disorder (PTSD) which impacted FBT. Additionally, clinicians felt their service-users were more complex than those in America where FBT was developed because service-users in the UK are not required to pay for treatment or insurance like in America, meaning that in the UK, FBT is also available to service-users of a low socioeconomic status. Clinicians expressed that this made some of their service-users more complex due to the additional vulnerabilities and needs of this population. Clinicians thought that because of the above complexities, FBT did not always fit with
what the families wanted or needed in an intervention, which made fidelity more difficult, reduced family buy-in to FBT and potentially contributed to dropout. Therefore, this subtheme overlaps with ‘lack of buy-in’ and ‘more co-morbidities’, generated as factors that contribute to dropout.

Access to resources

All clinicians had access to and utilised the manual. Most were aware that other resources were provided, however, reported that they could not be accessed due to not being allowed to use OneDrive. Clinicians expressed a desire to access the resources but thought that it was inappropriate to use their personal time for this.

Facilities

Facilities were a challenge in clinicians’ delivery of FBT, mainly for family meal sessions. Rooms do not have tables at the right height, enough chairs, cutlery, crockery, microwaves to heat food and are not family friendly. Clinicians thought that because of the facilities, they were less able to replicate the home environment or meal the CYP may eat at home, meaning that it was harder to challenge the AN.

Confusion surrounding additional support

There was confusion regarding additional support available to clinicians. Some clinicians were aware that they could take FBT cases to case discussion, however, others were unaware that this was permitted.

Table 3: Themes, subthemes and evidence relating to clinicians’ experiences.

<table>
<thead>
<tr>
<th>Theme</th>
<th>Subtheme</th>
<th>Supporting Evidence</th>
</tr>
</thead>
</table>
| Positive Experiences | Structure is containing | “It’s containing as there’s a nice structure to the manual so it feels like you can do it well even when it is new to you.”  
Participant 2 |
|         |                   | “It’s given me a structure and framework to work within.”  
Participant 7 |
|         | Empowers families | “Some families are not confident and have felt completely disempowered and paralysed by the anorexia. Parent |

Prepared on the Leeds D.Clin.Psychol. Programme, 2019
<table>
<thead>
<tr>
<th>Service Evaluation Project</th>
<th>Exploring Clinician’s Experiences of Delivering FBT</th>
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<tbody>
<tr>
<td></td>
<td>empowerment is key.” Participant 1</td>
</tr>
<tr>
<td></td>
<td>“the aim is to empower the parents again, which felt really positive.” Participant 6</td>
</tr>
<tr>
<td></td>
<td>“handing the responsibility back to the parents is empowering.” Participant 5</td>
</tr>
<tr>
<td></td>
<td>“It works well and is fantastic as it empowers the family from the start [...] It’s helpful that we are seen as the expert, but we are telling the parents that they know what their child needs to survive so they do not become dependent on the therapist.” Participant 2</td>
</tr>
<tr>
<td></td>
<td>“Some families are not confident and have felt completely disempowered and paralysed by the anorexia. Parent empowerment is key.” Participant 1</td>
</tr>
<tr>
<td>Value of supervision</td>
<td>“Supervision is brilliant. They’ve seen it all before and we can share our experiences. They [the supervisor] are passionate...” Participant 4</td>
</tr>
<tr>
<td></td>
<td>“supervision helps you to decide which phase you are in. It’s weekly and you learn a lot from other people’s cases [...] people are at different stages of experience, so you learn from other members” Participant 7</td>
</tr>
<tr>
<td></td>
<td>“Supervision holds you to something. You can check things out and test them. It’s invaluable and gets us to learn from each other’s cases.” Participant 2</td>
</tr>
<tr>
<td>Increased confidence over time</td>
<td>“I got better over time and as my confidence grew.” Participant 4</td>
</tr>
<tr>
<td></td>
<td>“I’ve become more confident and skilled at FBT through learning and practice.” Participant 5</td>
</tr>
<tr>
<td></td>
<td>“In the beginning I was learning everything, and it felt clunky. I’m more skilled in delivering it now [...] having exposure and a lot of cases for practice and supervision helped.” Participant 7</td>
</tr>
<tr>
<td>Challenges</td>
<td>Fidelity is difficult</td>
</tr>
<tr>
<td></td>
<td>“You can slip into other modalities. I have to make a conscious effort to stick to the manual.” Participant 2</td>
</tr>
</tbody>
</table>
“it goes against my instincts as a clinician to be flexible and adaptive.”  **Participant 1**

“I sometimes step out of the model. It can feel quite restrictive […] It feels more natural to me to bring in other bits of therapy if they are complex.”  **Participant 6**

“It’s a useful resource, but it doesn’t help if you go off piste.”  **Participant 2**

“there isn’t as much trouble shooting if things go wrong so it’s hard to know how to stick to the manual.”  **Participant 5**

“I gauge it in the session and bring in other skills e.g. a CBT experiment or motivational interviewing if the young person is stuck.”  **Participant 3**

“I do try to stay on the model though. I re-read chapters when we’re moving between phases, when I feel unsure or when I’m feeling stuck.”  **Participant 6**

“you want to go away and do something else for a session, but I try not to and take it to supervision.”  **Participant 2**

“Perhaps in our setting we get more complex cases than what the model was developed for […] You should be allowed to modify FBT for the service you are in […] I’m not a complete convert because it doesn’t fit for everyone.”  **Participant 7**

“the frustration is that our setting is away from the pure setting in America. The service users are different because they pay for treatment over there or can afford insurance. Here, people’s socioeconomic status is different and they are more complex, but they DNA because they aren’t directly paying for sessions”  **Participant 2**

“What’s less good is fitting individual circumstances to the model […] We need to in the long term be conscious that it doesn’t fit for everyone or every family”  **Participant 2**

“some people who self-harm need additional 1:1 work like DBT self-soothe skills which is more than what FBT can offer.”  **Participant 5**
Access to resources

“We’ve been sent a link to OneDrive, but we’re not allowed to use OneDrive so we would have to access them from home […]. We’ve paid for resources we can’t access.” Participant 1

Facilities

“We have no plates, no cutlery, nowhere to heat things up. A table that they can all sit around and a microwave would make a huge difference.” Participant 1

“We don’t have food preparation facilities which limits what the family can do and it’s harder to bring anorexia into the room.” Participant 2

“There’s nowhere to prep food and the rooms are too small […] Better facilities would have helped the family meal, the rooms don’t have toys in them, they aren’t family friendly, the chairs aren’t all the same size.” Participant 4

Confusion regarding additional support

“I ask people with more experience than me, like informal peer support. You can also take it to case discussion if you’re feeling stuck.” Participant 6

“I talk to my colleagues, but maybe we need to think about it as it would be useful to have a more formal space for discussion […] It would be good to have peer supervision to discuss the complex cases where doing FBT is harder.” Participant 1

Peer supervision would be helpful as we have similar cases, but I wouldn’t bring an FBT case to case discussion.” Participant 2

What do clinicians think contributed to early discontinuation (dropout) of FBT?

In most cases discussed, early discontinuation (dropout) occurred following joint discussions between clinicians and families when it was clear there were difficulties with FBT. Therefore, themes and subthemes reflect factors that clinicians thought contributed to difficulties with FBT and subsequently the decision to discontinue treatment early. This question generated three themes and seven subthemes (see table 4 for evidence).
Theme 1: Young Person

Clinicians thought that factors associated with the CYP impacted upon decisions to discontinue FBT. This theme consisted of three subthemes: ‘age’, ‘lack of weight restoration in the first four weeks’ and ‘more co-morbidities’.

Age
Clinicians reported that older individuals (15-17-year olds) found it difficult to engage in phase 1 of FBT because parents take control of re-feeding. Clinicians though that this age-group found parental control difficult because it is more age-appropriate for them to be independent in eating. Clinicians believed that this step-back in independence led to difficulties with the CYP’s engagement and increased their resistance, which prevented weight restoration and subsequently parental belief in FBT. Additionally, clinicians noted that older individuals expressed a desire for one-to-one therapy instead of FBT.

Lack of weight restoration in first four weeks
Clinicians reported that where the CYP did not weight restore at the suggested rate, this reduced parental buy-in to the effectiveness of FBT (see ‘lack of buy-in’) and increased their motivation to discontinue treatment as they felt it was not working. One clinician also noted that lack of weight restoration sometimes led to hospitalisation of the CYP and therefore the discontinuation of FBT as they needed more intensive support.

More co-morbidities
Some clinicians expressed that individuals with additional co-morbidities such as self-harm or post-traumatic stress disorder (PTSD) had more complex needs than those FBT was developed for (see ‘complexity of service users, no ‘one fit for all’ and ‘fidelity is difficult’). Clinicians felt these difficulties shifted the focus of sessions away from the ED towards managing risk, which reduced fidelity to FBT. Furthermore, clinicians reported that where pressure to weight-restore amplified risk i.e. increased self-harming, families and clinicians agreed to discontinue FBT to manage the risk. However, some clinicians thought that the addition of 1:1 therapy for individuals with co-morbidities may have helped to manage the risk and reduce dropout.
Theme 2: Parents

Clinicians thought that factors related to parents contributed to decisions to discontinue FBT. Two subthemes were generated: ‘lack of buy-in’ and ‘lack of confidence in themselves’.

Lack of buy-in

All clinicians referred to the importance of parental buy-in, highlighting that when buy-in was low, families struggled with FBT, lacked commitment and dropped out. There were three areas clinicians thought parental buy-in could be lacking. First, clinicians thought that some parents do not believe in the concept of mental health due to cultural or religious beliefs. Second, clinicians thought that some parents do not agree with the diagnosis of AN and therefore collude with it. Third, clinicians thought some parents do not buy-into FBT itself because they are not convinced it is effective. Some clinicians believed that lack of buy-in was related to the assessment process. The assessment can take hours and at the end, the CYP is given a diagnosis and FBT is recommended as the most effective treatment. Clinicians wondered whether the parent’s lack of buy-in to FBT was related to the lack of choice of treatment and/or lack of knowledge about what FBT entails, as it is difficult to remember and process verbal information at the end of the long assessment. Clinicians thought written information would be useful.

Lack of confidence in themselves

Some clinicians thought that when parents lacked confidence in themselves, especially in relation to re-feeding, families were more likely to stop attending. Clinicians felt that confidence could be boosted when parents had additional support (see ‘supported’ in relation to factors that increase likelihood of RIT).

Theme 3: Family

Clinicians though that factors related to the family contributed to dropout. Two subthemes were generated: ‘other concerns/problems’ and ‘lack of commitment’.
**Other concerns/problems**

Clinicians expressed that families who had complex dynamics where parents were not willing to support one-another or attend sessions together were more likely to drop out. Furthermore, clinicians thought that families who had other concerns such as moving house, parental divorce, financial difficulties or parental mental health difficulties had less capacity to prioritise FBT. This resulted in a lack of commitment (see below).

**Lack of commitment**

FBT requires not only commitment to weekly appointments, but a commitment to lifestyle changes. Clinicians thought that families who were unwilling or unable to do this due to other priorities (above) were more likely to dropout. Clinicians also attributed this lack of commitment to the parent’s lack of buy-in to the effectiveness of FBT.

**Table 4: Themes, subthemes and evidence for question 2.**

<table>
<thead>
<tr>
<th>Theme</th>
<th>Subtheme</th>
<th>Supporting Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Young person</td>
<td>Age (older)</td>
<td>“It felt developmentally out of kilter for the older kids.” <strong>Participant 4</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>“It’s because it feels like a step back in their independence.” <strong>Participant 1</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>“At about 17 they are at the age where they want individual 1:1 time and they want their independence to be respected. Age is a big factor.” <strong>Participant 2</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>“when they didn’t weight restore it made it harder and impacted the family buy-in.” <strong>Participant 4</strong></td>
</tr>
<tr>
<td>Lack of weight restoration in first 4 weeks</td>
<td></td>
<td>“if there isn’t quick progress of change in weight then the families lose faith in the model.” <strong>Participant 6</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>“some with really low weight go into hospital and some get referred to home based treatment where the treatment is completely different to FBT.” <strong>Participant 4</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>“when they didn’t weight restore it made it harder and impacted the family buy-in.” <strong>Participant 4</strong></td>
</tr>
</tbody>
</table>
### More co-morbidities

“...when the individual is not so well and has other co-morbidities such as self-harm. It impacts because of the general chaos that happens in the family. The parents are anxious, so the safety of the young person becomes the priority and you end up talking about this in FBT which takes the focus away from food.” **Participant 3**

“Risk can take over, for example, if someone self-harms or is suicidal. When they were asked to eat the risk increased so we had to stop FBT to manage the risk.” **Participant 2**

“Personally, I think they need 1:1 therapy too, especially when they have co-morbidities [...] some people who self-harm need additional 1:1 work like DBT self-soothe skills which is more than what FBT can offer.” **Participant 5**

### Parents

#### Lack of buy-in

Lack of buy-in to mental health:

“mum didn’t buy-into mental health because of her cultural beliefs and superstitions so she didn’t buy-in to the idea they she should be in control [...] mum then refused to come.” **Participant 6**

Lack of buy-in to the diagnosis:

“Some parents don’t buy-in to the diagnosis of anorexia so we struggle through the whole process [...] it just colludes with anorexia and this impacts upon weight restoration which then impacts all of FBT.” **Participant 1**

“you can see from the initial assessment the families that don’t accept the diagnosis or think that their child isn’t thin enough to be anorexic. So they come because they are recommended to rather than come themselves.” **Participant 6**

“Some parents don’t think that the low weight is a big deal, so they don’t come to some appointments.” **Participant 4**

“For one case, the parents weren’t on board right from the beginning. They said we were making a fuss of nothing and eventually dropped out.” **Participant 5**

“one family refused the family meal because they
Lack of buy-in to FBT:
“It’s something about families, especially parents not buying into the model. Families don’t have much of a choice. We don’t really offer an alternative to FBT after giving a diagnosis of anorexia and families just say ‘ok you’re the expert’ and just go along with it [...] They only get verbal information on FBT at assessment which is 3-4 hours. We should finalise the leaflets so families can go away and process it so they can make more of an informed decision on if FBT is right for them.” Participant 1

“I think the parents buy-in is related to the assessment. They don’t get much information at assessment and we need to look at the accessibility of our leaflets so that people can go away and make an informed choice.” Participant 2

“We present FBT as a recommendation but should make sure we offer an alternative if they are unsure, but with the caveat that it may not be as effective.” Participant 6

Lack of confidence in themselves
“Some parents feel as though they can’t re-feed their child, despite the model and the support. The first few weeks are hard, and they come back worried, so we need support to give them a confidence boost.” Participant 1

Family Other concerns/priorities
“In the families where the eating disorder is not the main problem, it makes FBT harder and more complex.” Participant 7

“The family decided they didn’t need it [FBT]. They were a complex family where they had separated and didn’t want to work together. I couldn’t get the parents to come at the same time.” Participant 2

“families need to be open to the idea of eating meals together and working as a unit. They need the willingness to work together, but sometimes the dynamics are too complex.” Participant 4
“sometimes families just move out of area.”
Participant 7

“the parents had their own mental health problems. They both suffered from depression and didn’t have the capacity for it [FBT]”. Participant 2

<table>
<thead>
<tr>
<th>Lack of commitment</th>
<th>“One parent stops coming as they’re unable to re-arrange their life around the FBT.” Participant 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“It’s the parent’s buy-in to making big changes early – showing the preparedness to make big changes to their life. Missing a session in the first month is linked to worse outcomes, like dropout.” Participant 2</td>
</tr>
<tr>
<td></td>
<td>“it’s something about getting both parents engaged – inconsistent attendance impacted.” Participant 3</td>
</tr>
</tbody>
</table>

What do clinicians think increases the likelihood of families remaining in treatment (RIT)?

This question generated five themes and thirteen subthemes (see table 5 for evidence).

**Theme 1: Young person**

Clinicians thought that factors associated with the CYP increased the likelihood of families RIT. This theme consisted of three subthemes: ‘age’, ‘lower initial weight’ and ‘lack of co-morbidities’

*Age*

Clinicians thought that younger individuals found the parent’s initial responsibility for weight restoration less unusual than older individuals because it is more developmentally appropriate for parents to control their eating. Therefore, there was less resistance and more compliance from the CYP. Clinicians felt this contributed to families RIT as the CYP would gain weight which increased parental confidence and buy-in to FBT.
**Lower initial weight**
Clinicians thought that CYP who started FBT at a lower weight were more likely to RIT because parents were more worried about the physical dangers. Clinicians thought that this anxiety was helpful as it mobilised parents into action and increased their initial commitment to FBT.

**Lack of comorbidities**
Clinicians reported that where CYP had fewer co-morbidities, FBT sessions were more focused on the ED and improvements to weight and ED cognitions could be seen quicker. Clinicians thought this increased parent’s buy-in to FBT which helped the family RIT.

**Theme 2: Parents**
Clinicians thought that factors associated with the parents had a huge contribution to the increased likelihood of families RIT. This theme consisted of two subthemes: ‘early buy-in to FBT’ and ‘supported’.

**Early buy-in to FBT**
Complimentary to clinicians’ thoughts that lack of buy-in contributes to dropout, they also believed that when parents buy-in to FBT earlier, families are more likely to RIT. Clinicians thought that initial buy-in was facilitated by the presentation of FBT’s evidence base in combination with the medical information relating to the CYP’s physical health and the dangers associated with this. Therefore, clinicians thought that parental buy-in was increased when the CYP had a lower initial weight because they were more concerned. Clinicians thought that this facilitated parent’s commitment to FBT and the lifestyle change, which resulted in weight restoration and maintained parental buy-in.

**Supported**
Clinicians thought that families where parents are supported by partners or grandparents are more likely to RIT. Clinicians mostly thought the support of a partner/wider family was helpful as it increased parental confidence and gave the YP consistent messages.
Additionally, some clinicians thought that parents who attended the parent’s group offered by the service were more likely to RIT because they could meet parents at different stages of FBT which provided hope and demonstrated its effectiveness.

**Theme 3: Family**

Clinicians thought factors relating to the family increased the likelihood of RIT. This theme consisted of three subthemes: ‘committed’, ‘no complex dynamics’ and ‘supportive’.

*Committed*

This mirrors the subtheme ‘lack of commitment’ as clinicians thought that families who bought in to FBT and were committed to sessions/making changes at home were more likely to RIT. One clinician highlighted that the CYP-EDS were considering implementing a review pathway to monitor commitment so that factors impacting commitment could be problem solved to support more families to RIT.

*No complex dynamics*

Mirroring clinicians’ thoughts that families who had other concerns/priorities contributed to dropout, they also believed that families with less complex dynamics were more likely RIT. This subtheme is closely related to the ‘supportive’ subtheme as clinicians thought that less difficult family dynamics made them more cohesive and supportive.

*Supportive*

Clinicians reported that where family such as grandparents (both those involved in FBT sessions and those not), were more supportive of parents, they were more likely to feel confident and RIT.

**Theme 4: Clinician**

Clinicians also thought that they contributed to increasing the likelihood of families RIT. This theme consisted of two overlapping subthemes: ‘belief in FBT’s effectiveness’ and ‘ability to ‘sell’ FBT’
Belief in FBT’s effectiveness

Clinicians thought their belief in FBT’s effectiveness aka buy-in impacts on whether a family RIT. Clinicians thought that alike other therapies, clinicians’ belief in FBT impacts upon their delivery of it and subsequently parental buy-in-commitment. Higher clinician buy-in was associated with a more convincing delivery of FBT and increased likelihood of families RIT. Some clinicians reported that their belief in FBT was aided by seeing the evidence base and having experiences where FBT facilitated change.

Ability to ‘sell’ FBT

Some clinicians thought that the better their ability to ‘sell’ FBT as effective, the more likely parents would buy-in early and maintain engagement. Clinicians reported that their ability to ‘sell’ FBT improved as they became more experienced and more confident that FBT is effective.

Theme 5: FBT

Clinicians thought that some features of FBT itself increased the likelihood of families RIT. This theme consisted of three subthemes: ‘evidence based’, ‘externalising and non-judgemental’ and ‘empowering’.

Evidence based

Clinicians felt that FBT’s evidence base aided their buy-in/confidence in FBT’s effectiveness and their ability to portray this to the family. Clinicians thought that the evidence base helped them to persist with delivering FBT rather than suggesting that it is not working for the family when there were challenges.

Externalising & non-judgemental

Clinicians reported that a barrier to RIT is parental fear of being judged. Additionally, clinicians thought that some parents are frustrated with their child and feel they are ‘being difficult’, which impacts their buy-in to the diagnosis and treatment. However, clinicians thought that FBT externalises anorexia which minimises judgement and blame. Therefore, clinicians thought this increases the likelihood of families RIT.
Empowering

See ‘empowers families’ for details of this subtheme.

Table 5: Themes, subthemes and supporting evidence for question 3.

<table>
<thead>
<tr>
<th>Theme</th>
<th>Subtheme</th>
<th>Supporting Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Young Person</td>
<td>Age (younger)</td>
<td>“It’s easier when the young person is younger because it’s more normal for a parent to tell an 11-year-old what to eat than someone older […] before anorexia, they weren’t responsible for feeding themselves so they are more compliant and gain weight and parents see the progress.”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“younger starting age is better. It’s more developmentally appropriate for FBT and for the parents to take control back.”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“younger children do better because they are more compliant and listen to their parents more.”</td>
</tr>
<tr>
<td>Lower initial weight</td>
<td></td>
<td>“for my cases, the lower weight they were when they came in, then the parents are more successful at re-feeding. The parents see the test results and think ‘shit’ because they can see how unwell their child is physically.”</td>
</tr>
<tr>
<td>Lack of co-morbidities</td>
<td></td>
<td>“When it’s worked well it was for those with pure anorexia and parents could see it working.”</td>
</tr>
<tr>
<td>Parents</td>
<td>Early buy-in to FBT</td>
<td>“It works well when parents are on board with the model from the start […] When parents buy-in to the model and take on board the messages about the dangers of anorexia. Also, when they take on board and implement the principles of FBT from the assessment and then can see it working.”</td>
</tr>
<tr>
<td></td>
<td>Supported</td>
<td>“…two parents work together, siblings attend and grandparents attend. It’s that extra people to talk to and”</td>
</tr>
</tbody>
</table>
checking if they feel they are doing something wrong, sharing tips about what works. It gives them extra confidence that they are doing things right.” **Participant 3**

“Where more family members are involved it’s better. One family had the grandparents onboard which supported the family. Everyone was doing the same thing even if they weren’t looking after the child at the same time. The consistent message was helpful.” **Participant 6**

“...both parents together and the role of the mum and dad supporting each other is hugely important in ensuring that they give the same messages to the child.” **Participant 2**

“families like to meet other families alongside FBT in the parent’s group. They needed hope from each other that FBT works and it helped them to hear other’s experiences.” **Participant 4**

<table>
<thead>
<tr>
<th>Family</th>
<th>Committed</th>
<th>“it works well when the whole family are committed and persevere with the model.” <strong>Participant 6</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>“Missing a session in the first month is linked to worse outcomes.” <strong>Participant 2</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>“a built-in review pathway might be useful after session 4 so that we can see how committed a family is.” <strong>Participant 2</strong></td>
</tr>
<tr>
<td>No complex dynamics</td>
<td></td>
<td>“those that continue with treatment have good family cohesion and they functioned well as a family before the ED came along.” <strong>Participant 2</strong></td>
</tr>
<tr>
<td>Supportive</td>
<td>Evidence for this subtheme can be taken from the ‘supported’ subtheme.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinician</th>
<th>Belief in FBT’S effectiveness</th>
<th>“you need to have faith in it [FBT] yourself to encourage parents to do so too.” <strong>Participant 3</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>“How confident the clinician is and their buy-in to FBT helps the parents feel confident” <strong>Participant 2</strong></td>
</tr>
<tr>
<td>Ability to ‘sell’ FBT to</td>
<td></td>
<td>“the therapist’s buy-in is important. It’s their confidence and belief in FBT and being able to convey this from the</td>
</tr>
</tbody>
</table>
family start which is helpful.” Participant 2

“the fact there’s an evidence base to present to families, feels more robust and you feel more confident in delivering it.”
Participant 7

“Clinicians’ confidence and competence in delivering the model is important.” Participant 4

**FBT** Evidence based

“It’s reassuring that it’s evidence based. It feels better and makes me more confident, more confident to stick with it and it reinforces to the family that it will work.” Participant 2

“Being able to show the parent’s the evidence base helps increase their buy-in.” Participant 7

Externalising & non-judgemental

“FBT is non-judgemental as it externalises the anorexia and says it could happen to anyone.” Participant 5

the externalising helps relieve the parents from guilt and shame of blaming themselves.” Participant 7

Empowering

See table 1 for evidence supporting his subtheme as it also fell under the theme ‘positive experiences’ for clinicians.

---

**Discussion**

The aims of the study were achieved as clinicians were given the opportunity to reflect upon their experiences of delivering FBT and discuss the factors they thought contributed to family’s dropout and RIT. Key findings are discussed below.

**Key findings**

Clinicians’ experiences of implementing FBT in the Leeds CYP-EDS are encouraging. All clinicians reported largely positive experiences and increased in confidence in
delivering FBT over time, with practice and support. The structure of the FBT manual, the core feature of parental empowerment and high-quality supervision contributed to clinicians’ positive experiences. Parental empowerment was also identified as something that contributes to families RIT, which is consistent with Dimitropoulos et al., (2017). Main challenges were related to the complexity of service users which impacted clinicians’ fidelity to FBT and their opinion that FBT is not always the most appropriate treatment. This supports the approach taken in the CYP-EDS’, which is that FBT does not ‘fit’ for all families and the aspiration to provide a stepped care model where clinicians are trained in additional therapies. This is concordant with the recommendation that if FT is not appropriate or has been problematic, then CBT or adolescent focused therapies should be offered (NICE, 2017).

The exploration of factors clinicians thought contributed to dropout and RIT generated themes relating to the CYP, parents, family, clinician and FBT itself. Each theme consisted of several subthemes. Key findings were consistent with research suggesting that parent’s perceptions that treatment is not effective contributes to dropout in FBT (Ellison et al., 2012). Findings were also consistent with research stating that family cohesiveness, weight gain by session four and therapist belief in FBT facilitates therapeutic change and encourages families to RIT (Blow, Sprenkle & Davis, 2007; Ellison et al., 2012). Strikingly, many subthemes were interlinked, which was evident in clinicians’ descriptions, so thematic maps were created in attempt to summarise and make sense of them (see figure 1). Clinicians described a link between parental buy-in, commitment and weight restoration which seemed to be central in dropout and RIT. The other factors/themes described (blue writing) appeared to impact upon this cycle.
Figure 1: Summary of factors impacting dropout and RIT.

- **Lack of buy-in** to mental health and the diagnosis
- **Difficulty taking in/processing information regarding FBT at assessment and lack of choice of treatment**: lack of buy-in to FBT

Lack of buy-in or belief in FBT’s effectiveness

- **Family/parents have other concerns/priorities**
- **Parent’s lack of confidence in themselves**
- **Lack of support**

**Dropout**

- **Evidence base increases clinician’s belief in FBT’s effectiveness**
- **Clinician’s belief in effectiveness enhances ability to ‘sell’ FBT to families**

**Parental buy-in to FBT**

- **Age (Younger) CYP = more compliant during weight restoration**
- **Lack of co-morbidities = more straightforward sessions**

**Therapeutic change: Weight restoration in 1st 4 weeks (and other progress)**

- **Committed**

- **CYP Lower initial weight + information on dangers of low weight increases anxiety in parents**
- **No complex family dynamics/more willing to work together and support one another**

- **More co-morbidities = less fidelity to FBT and lack of focus on ED in sessions**
- **FBT less effective/less therapeutic change e.g. less weight restoration/changes to ED cognitions**

**Dropout**

- **Age (Older) CYP = resistance in weight restoration**
To conclude, findings demonstrate that clinicians thought several factors occur concurrently, influencing likelihood of dropout or RIT. Some of these factors are beyond the control of the service e.g. age of CYP referred. However, the CYP-EDS could make some changes to influence some factors (see recommendations).

Strengths and limitations

Results should be considered in the context of the study’s strengths and limitations. First, a strength of the method is that the semi-structured interviews allowed the research questions to be explored in depth, whilst being responsive to clinicians’ reflections. This helped provide a rich account which may have been stifled by a structured interview. Second, a strength in the thematic analysis is the credibility check where the team assessed and confirmed face validity of the themes. Finally, a strength in the interpretation of the results is that a thematic map was developed to summarise the links between subthemes that clinicians described. This was an attempt to further understanding regarding how the subthemes contribute to dropout/RIT, which goes beyond the aims of the study. This has hopefully provided the CYP-EDS with a greater understanding of dropout and RIT in their service and helped to inform recommendations.

However, it is important to acknowledge that qualitative research takes place within the context of the researcher’s own values, beliefs and assumptions and therefore may have impacted upon the organisation and understanding of themes (Denzin & Lincoln, 1994). For example, having worked with women with complex ED’s in the past, the researcher holds a similar belief to the one presented by the clinicians interviewed i.e. that it is more difficult to maintain fidelity to one approach when individuals present with more co-morbidities, which may mean there is less focus and treatment is less effective. This may be why this idea is seen as an important theme as it confirms the researcher’s belief. As a result, the thematic maps are intended to be tentative suggestions about how the themes/subthemes may combine to increase the likelihood of dropout or RIT, rather than being concrete ideas.
A limitation of the study is that families were not interviewed regarding their reasons for dropout or RIT. Even though clinicians provided mostly consistent opinions, which suggests reliability, there was no evidence of a theme suggesting that factors relating to clinicians contributed to dropout. This is surprising given that research highlights that a poor therapeutic alliance in FT and individual therapy contributes to dropout (Robbins et al., 2003; Samstag et al., 1998) and that clinicians in this study thought they contributed to RIT. This highlights that there may have been an element of bias in the clinicians’ opinions, therefore, it would be beneficial to interview families to offer an alternative perspective.

**Recommendations**

*Figure 2: Recommendations to the service.*

The following recommendations are suggested based on the results and the idea that intervening at different points on the thematic map might prevent dropout or increase the likelihood of families RIT:

- To interview the families and young people in order to gain their perspective on reasons for dropout of FBT and factors that increase their likelihood of persisting with treatment.
- The service is now implementing a pathway where cases are reviewed every 4-6 weeks to reduce drift and enhance fidelity to FBT. It may be helpful that within the review pathway the young person’s age, weight at point of referral and the rate at which they gained weight in the first four weeks of FBT are considered, as these are possible indicators of success and impact parental buy-in.
- Provide families with written information regarding the effectiveness of FBT and what the treatment involves (at assessment) in order to facilitate initial buy-in and commitment to the treatment.
- Clinicians to continue to use supervision to maintain fidelity to FBT. Ensure all staff are aware that case discussion is also a space to seek support for complex FBT cases.
- Clinicians who feel less confident in explaining what FBT involves and
presenting the evidence to families could seek extra support for this via supervision or case discussion.

➢ Clinicians to encourage parents to attend the parent support group, especially if they are struggling to buy-in to the effectiveness of FBT.

➢ Ensure the additional resources on One Drive are uploaded to the shared drive so Clinicians can access them at work.

➢ Ideally, improvements could be made to facilities available for the family meal so that hot food can be prepared e.g. a table at the correct height, a microwave, cutlery. However, other factors such as funding, risk and the shared nature of clinic spaces would first need to be considered.

Dissemination

Initial findings were presented to the CYP-EDS at a team meeting. Findings were also disseminated via a poster (appendix 5) and presentation at a conference held by the University of Leeds Doctorate in Clinical Psychology course in October 2019. The full report has been shared with the service.
References


Appendices

Appendix 1: Study’s ethics application.

UNIVERSITY OF LEEDS RESEARCH ETHICS COMMITTEE APPLICATION FORM

Please read each question carefully, taking note of instructions and completing all parts. If a question is not applicable please indicate so. The superscripted numbers (eg \(^8\)) refer to sections of the guidance notes, available at http://ris.leeds.ac.uk/uoethicsapplication. Where a question asks for information which you have previously provided in answer to another question, please just refer to your earlier answer rather than repeating information. Research ethics training courses: http://www.sddu.leeds.ac.uk/research-innovation/research-ethics-training-and-guidance

To help us process your application enter the following reference numbers, if known and if applicable:

<table>
<thead>
<tr>
<th>Ethics reference number:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Student number and/ or grant reference:</td>
<td>200604200</td>
</tr>
</tbody>
</table>

PART A: Summary

A.1 Which Faculty Research Ethics Committee would you like to consider this application?\(^2\)

- Arts, Humanities and Cultures (PVAR)
- ESSL/ Environment/ LUBS (AREA)
- MaPS and Engineering (MEEC)
- Medicine and Health (Please specify a subcommittee):
  - School of Dentistry (DREC)
  - School of Healthcare (SHREC)
  - School of Medicine (SoMREC)
  - School of Psychology (SoPREC)

A.2 Title of the research\(^3\)

Maximising the utility of FBT – Identifying the factors that impact upon the outcome
(I am defining outcome as treatment completion/remaining in treatment/weight restoration/reduction in EDE-Q to below the clinical cut off)
A.3 Principal investigator’s contact details

<table>
<thead>
<tr>
<th>Name (Title, first name, surname)</th>
<th>Maria Lucy Siena</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position</td>
<td>Psychologist in Clinical Training</td>
</tr>
<tr>
<td>Department/ School/ Institute</td>
<td>Leeds Institute of Health Sciences</td>
</tr>
<tr>
<td>Faculty</td>
<td>Faculty of Medicine and Health</td>
</tr>
<tr>
<td>Work address (including postcode)</td>
<td>Programme in Clinical Psychology</td>
</tr>
<tr>
<td></td>
<td>Leeds Institute of Health Sciences</td>
</tr>
<tr>
<td></td>
<td>Level 10, Worsley Building</td>
</tr>
<tr>
<td></td>
<td>Clarendon Road</td>
</tr>
<tr>
<td></td>
<td>Leeds, LS2 9NL</td>
</tr>
<tr>
<td>Telephone number</td>
<td>0113 3430815</td>
</tr>
<tr>
<td>University of Leeds email address</td>
<td><a href="mailto:ps11mls@leeds.ac.uk">ps11mls@leeds.ac.uk</a></td>
</tr>
</tbody>
</table>

A.4 Purpose of the research: (Tick as appropriate)

- Research
- Educational qualification: Please specify: ___Doctorate in Clinical Psychology___
- Educational Research & Evaluation
- Medical Audit or Health Service Evaluation
- Other
A.5 Select from the list below to describe your research: (You may select more than one)

- ✔ Research on or with human participants
- ✔ Research which has potential adverse environmental impact. If yes, please give details:

□ Research working with data of human participants
- ✔ New data collected by qualitative methods
- ✔ New data collected by quantitative methods
- ✔ New data collected from observing individuals or populations
- ✔ Routinely collected data or secondary data
- ✔ Research working with aggregated or population data
- ✔ Research using already published data or data in the public domain
- ✔ Research working with human tissue samples (Please inform the relevant Persons Designate if the research will involve human tissue)

A.6 Will the research involve NHS staff recruited as potential research participants (by virtue of their professional role) or NHS premises/ facilities?

- ✔ Yes
- □ No

If yes, ethical approval must be sought from the University of Leeds. Note that approval from the NHS Health Research Authority may also be needed, please contact FMHUniEthics@leeds.ac.uk for advice.

A.7 Will the research involve any of the following: (You may select more than one)

If your project is classified as research rather than service evaluation or audit and involves any of the following an application must be made to the NHS Health Research Authority via IRAS www.myresearchproject.org.uk as NHS ethics approval will be required. There is no need to complete any more of this form. Further information is available at http://ris.leeds.ac.uk/NHSethicalreview and at http://ris.leeds.ac.uk/HRAapproval. You may also contact governance-ethics@leeds.ac.uk for advice.

- □ Patients and users of the NHS (including NHS patients treated in the private sector)
- □ Individuals identified as potential participants because of their status as relatives or carers of patients and users of the NHS
- □ Research involving adults in Scotland, Wales or England who lack the capacity to consent for themselves
A prison or a young offender institution in England and Wales (and is health related)  
Clinical trial of a medicinal product or medical device  
Access to data, organs or other bodily material of past and present NHS patients  
Use of human tissue (including non-NHS sources) where the collection is not covered by a Human Tissue Authority licence  
Foetal material and IVF involving NHS patients  
The recently deceased under NHS care  
None of the above
You must inform the Research Ethics Administrator of your NHS REC reference and approval date once approval has been obtained.

The HRA decision tool to help determine the type of approval required is available at http://www.hra-decisiontools.org.uk/ethics. If the University of Leeds is not the Lead Institution, or approval has been granted elsewhere (e.g. NHS) then you should contact the local Research Ethics Committee for guidance. The UoL Ethics Committee needs to be assured that any relevant local ethical issues have been addressed.

A.8 Will the participants be from any of the following groups? (Tick as appropriate)

- Children under 16  
- Adults with learning disabilities  
- Adults with other forms of mental incapacity or mental illness  
- Adults in emergency situations  
- Prisoners or young offenders  
- Those who could be considered to have a particularly dependent relationship with the investigator, eg members of staff, students  
- Other vulnerable groups  
- No participants from any of the above groups

Please justify the inclusion of the above groups, explaining why the research cannot be conducted on non-vulnerable groups.

It is the researcher’s responsibility to check whether a DBS check (or equivalent) is required and to obtain it if needed. See also http://www.homeoffice.gov.uk/agencies-public-bodies/dbs and
A.9 Give a short summary of the research\(^{18}\)

This section must be completed in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol, although the protocol can also be submitted to provide any technical information that you think the ethics committee may require. This section should cover the main parts of the proposal.

The Leeds Children and Young People Eating Disorder Service introduced Family Based Treatment (FBT) in September 2017. So far, six members of staff have delivered FBT and are receiving clinical supervision within the service. This service evaluation project aims to interview these members of staff (semi-structured interviews) regarding their experiences of delivering FBT. Staff will also be asked about what factors they consider when suggesting a family is appropriate/suitable for FBT. Also, what contributes to the decision to discontinue FBT for certain families and what factors they think contributes to families remaining in treatment/completing treatment.

The interviews will be analysed using thematic analysis which means that the investigator will attempt to recognise themes in what the clinicians report to gain an overview of the topics discussed. It is hoped that the results of this service evaluation project will enable recommendations to be made to the service regarding the delivery of FBT.

A.10 What are the main ethical issues with the research and how will these be addressed?\(^{19}\)

Indicate any issues on which you would welcome advice from the ethics committee.

**Informed consent:** Participants will be given an information sheet (see attached) which will outline the aim of the research and what their part in the research will involve. Participants will be given the opportunity to ask any questions and if they agree to take part they will be given the consent form to sign (see attached). They will be asked to sign two copies (one which will be retained by the principal investigator and kept in a locked cabinet and one that they will keep).

**Right to withdraw:** The information sheet refers to a participant’s right to withdraw and explains this process to them. It states: “Participation in the service evaluation project is voluntary and should you not wish to take part, there will be no consequences” and “You can withdraw at any point (up until 1 week after your interview when data will have been incorporated into the analysis) without having to provide a reason and without any consequences. It will not be possible to withdraw data after this point as it will have been incorporated into the analysis. Should you not wish to answer any question within the interview, you are free to decline.” The information sheet also explains the process of withdrawal and what will happen if they have taken part in the interview: “If you do wish to withdraw before, during or after your interview, please contact Lucy Siena at
Any data provided before withdrawal will be discarded (notes will be disposed of in confidential waste).

Confidentiality and Anonymity: Participants will not be fully anonymous to the interviewer as these will be face to face. The information sheet describes how anonymity and confidentiality will be sought: “Written notes taken in the interview will be anonymised so that they do not contain any identifiable information. These notes will be assigned a code known only to Lucy Siena so that your name is not matched to the interview notes. The code is required only in case you wish to withdraw your data within 1 week of the interview. All notes will be kept confidential and stored in a locked draw or cabinet. The only occasion when confidentiality may be broken is if you disclose information that suggests that you pose a risk to yourself or others (including unsafe practice). If this situation arises then this will be discussed with you and may need to be discussed with a more senior member of the team.

Sensitive data: Participants are asked to talk openly and honestly about their experiences of delivering FBT. There is a possibility that the analysis will include negative as well as positive themes. The information sheet highlights that participant’s responses will be kept confidential (in a locked cabinet or draw) and anonymous and that understanding possible negative themes will likely be incorporated into improving the delivery of FBT across the service.

### PART B: About the research team

<table>
<thead>
<tr>
<th>B.1 To be completed by students only&lt;sup&gt;20&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qualification working towards (eg Masters, PhD)</td>
</tr>
<tr>
<td>Supervisor’s name (Title, first name, surname)</td>
</tr>
<tr>
<td>Department/ School/ Institute</td>
</tr>
<tr>
<td>Faculty</td>
</tr>
</tbody>
</table>
| Work address (including postcode) | Programme in Clinical Psychology  
Leeds Institute of Health Sciences  
Level 10, Worsley Building  
Clarendon Road  
Leeds, LS2 9NL |
| Supervisor’s telephone number | 0113 343 2736 |
| Supervisor’s email address | g.latchford@leeds.ac.uk |
| Module name and number (if N/A) | N/A |
B.2 Other members of the research team (eg co-investigators, co-supervisors) 21

<table>
<thead>
<tr>
<th>Name (Title, first name, surname)</th>
<th>Dr Julie Franklin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position</td>
<td>Consultant Clinical Psychologist</td>
</tr>
<tr>
<td>Department/ School/ Institute</td>
<td>CAMHS Eating Disorders (Leeds Community Healthcare NHS Trust)</td>
</tr>
<tr>
<td>Faculty</td>
<td>N/A</td>
</tr>
<tr>
<td>Work address (including postcode)</td>
<td>Reginald Centre 263 Chapeltown Rd, Leeds LS7 3EX</td>
</tr>
<tr>
<td>Telephone number</td>
<td>0113 ...</td>
</tr>
<tr>
<td>Email address</td>
<td><a href="mailto:julie.franklin@nhs.net">julie.franklin@nhs.net</a></td>
</tr>
</tbody>
</table>

Part C: The research

C.1 What are the aims of the study? 22 (Must be in language comprehensible to a lay person.)

- To provide staff with the opportunity to reflect upon their experiences of delivering FBT to increase understanding of how FBT is being delivered within the service.
- To investigate what factors clinicians think impacts on early discontinuation of FBT.
- To investigate what factors clinicians think enables families to remain in FBT/complete FBT.
- To consider all this information with a view to providing recommendations to the
C.2 Describe the design of the research. Qualitative methods as well as quantitative methods should be included. (Must be in language comprehensible to a lay person.)

It is important that the study can provide information about the aims that it intends to address. If a study cannot answer the questions/add to the knowledge base that it intends to, due to the way that it is designed, then wasting participants’ time could be an ethical issue.

Semi-structured interviews with clinicians will be carried out. Questions will be very open to begin with and then follow up questions will be asked (these questions will be guided by the participant’s responses). See attached interview schedule for initial questions and possible follow up questions. A thematic analysis will be carried out to reach the aims of the study and answer the research question (Braun & Clarke, 2006).


C.3 What will participants be asked to do in the study? (e.g. number of visits, time, travel required, interviews)

Participants will be asked to take part in a 1:1 interview with the principal investigator which will last approximately 1 hour. The interview will take place at the Reginald Centre (participant’s place of work).

Participants will be asked to answer questions openly and honestly, however the information sheet does specify that should participants not wish to answer any questions then they can decline to answer.

C.4 Does the research involve an international collaborator or research conducted overseas?

(Tick as appropriate)

☐ Yes  ☑ No

If yes, describe any ethical review procedures that you will need to comply with in that country:
Describe the measures you have taken to comply with these:

Include copies of any ethical approval letters/ certificates with your application.

C.5 Proposed study dates and duration

Research start date (DD/MM/YY): __07/01/19   Research end date (DD/MM/YY): 13/11/19

Fieldwork start date (DD/MM/YY): __07/01/19   Fieldwork end date (DD/MM/YY): 13/10/19

C.6. Where will the research be undertaken? (i.e. in the street, on UoL premises, in schools)

The Reginald Centre (in a meeting room)
263 Chapeltown Rd, Leeds LS7 3EX

RECRUITMENT & CONSENT PROCESSES

How participants are recruited is important to ensure that they are not induced or coerced into participation. The way participants are identified may have a bearing on whether the results can be generalised. Explain each point and give details for subgroups separately if appropriate.

C.7 How will potential participants in the study be:

(i) identified?

Participants will be clinicians who are currently delivering or who have delivered FBT within the service. There are 6 possible participants. Participants are aware of the service evaluation project and have already expressed to the commissioner that they wish to take part in the interviews, therefore, we do not anticipate any difficulties with recruitment.

(ii) approached?

Participants are already aware that the service evaluation will be taking place and have expressed a willingness to take part. Participants will be approached face to face in their place of work by the principal investigator to be given the information sheet and consent
(iii) recruited?26

If participants are happy to arrange an interview time when then are approached with the information sheet/consent form, then this will be arranged. However, if participants would like more time to consider their decision before signing the consent form and arranging the interview then the participants will be asked whether they would prefer to contact the principal investigator by email or whether they would like the principal investigator to contact them via email.

C.8 Will you be excluding any groups of people, and if so what is the rationale for that?27

Excluding certain groups of people, intentionally or unintentionally may be unethical in some circumstances. It may be wholly appropriate to exclude groups of people in other cases

Anyone within the service who has not delivered FBT. This is to ensure that the aims/research question can be answered.

C.9 How many participants will be recruited and how was the number decided upon?28

It is important to ensure that enough participants are recruited to be able to answer the aims of the research.

6 – this is the number of Clinicians who have delivered FBT within the service. This number was not derived from the literature – the aim is to interview all clinicians who have delivered FBT within the service, so this number has been determined by the number of people trained in FBT and delivering it in the service.


If you have a formal power calculation please replicate it here.

Remember to include all advertising material (posters, emails etc) as part of your application
C10 Will the research involve any element of deception?²⁹
If yes, please describe why this is necessary and whether participants will be informed at the end of the study.

No.

C.11 Will informed consent be obtained from the research participants?³⁰
☑ Yes  □ No
If yes, give details of how it will be done. Give details of any particular steps to provide information (in addition to a written information sheet) e.g. videos, interactive material. If you are not going to be obtaining informed consent you will need to justify this.

Participants will be approached at their place of work to be given the information sheet and consent forms (see attached). Participants will be given the choice of signing the consent form after reading the information sheet or whether they would like more time to consider the information. If they would like more time to consider the information then they will be asked whether they would like to contact the investigator or whether they would like the investigator to contact them again after a specified amount of time. Participants will sign two consent forms – one which will be kept in a locked cabinet and one which they will retain.

The information sheet will state:

“Participation in the service evaluation project is voluntary and should you not wish to take part, there will be no consequences. If you decide to take part, you will be given this information sheet and will be asked to sign a consent form which you will also be given a copy of. You can withdraw at any point (up until 1 week after your interview when data will have been incorporated into the analysis) without having to provide a reason and without any consequences. It will not be possible to withdraw data after this point as it will have been incorporated into the analysis. Should you not wish to answer any question within the interview, you are free to decline.”

If participants are to be recruited from any of potentially vulnerable groups, give details of extra steps taken to assure their protection. Describe any arrangements to be made for obtaining consent from a legal representative.

Copies of any written consent form, written information and all other explanatory
**material should accompany this application.** The information sheet should make explicit that participants can withdraw from the research at any time, if the research design permits. Remember to use meaningful file names and version control to make it easier to keep track of your documents. Sample information sheets and consent forms are available from the University ethical review webpage at [http://ris.leeds.ac.uk/InvolvingResearchParticipants](http://ris.leeds.ac.uk/InvolvingResearchParticipants).

**C.12 Describe whether participants will be able to withdraw from the study, and up to what point (eg if data is to be anonymised). If withdrawal is not possible, explain why not.**

Any limits to withdrawal, eg once the results have been written up or published, should be made clear to participants in advance, preferably by specifying a date after which withdrawal would not be possible. Make sure that the information provided to participants (eg information sheets, consent forms) is consistent with the answer to C12.

The information sheet and consent forms will state that participants will be free to withdraw at any point before, during or after the interview (up to 1 week after the interview when data will have been incorporated into the analysis). It states that if any data has been provided (written notes) then this will be disposed of in confidential waste.

**C.13 How long will the participant have to decide whether to take part in the research?**

It may be appropriate to recruit participants on the spot for low risk research; however consideration is usually necessary for riskier projects.

Participants will be approached at their place of work to be given the information sheet (see attached). Participants will be given the choice of signing the consent form after reading the information sheet or whether they would like more time to consider the information. If they would like more time to consider the information then they will be asked whether they would like to contact the investigator or whether they would like the investigator to contact them again after a specified amount of time.

**C.14 What arrangements have been made for participants who might have difficulties understanding verbal explanations or written information, or who have particular communication needs that should be taken into account to facilitate their involvement in the research?**

Different populations will have different information needs, different communication abilities and different levels of understanding of the research topic. Reasonable efforts should be made to include potential participants who could otherwise be prevented from participating due to disabilities or language barriers.

Participants are clinicians delivering FBT to families in England. They have good written and verbal English skills as this is required in the delivery of therapy, liaison with other staff members and report writing within the service.
C.15 Will individual or group interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could take place during the study (e.g. during interviews or group discussions)?

The information sheet should explain under what circumstances action may be taken.

☑ Yes    ☐ No    If yes, give details of procedures in place to deal with these issues.

Participants will be asked about their experiences of delivery of FBT within the service which could be difficult if they have had a negative experience of its delivery. The investigator/interviewer is a Psychologist in Clinical Training with experience in sensitively managing situations where individuals may be experiencing difficult emotions. The information sheet states that participants do not have to answer questions they do not wish to, and the interviewer will use clinical judgement if they feel that a participant appears to not want to answer a question. The information sheet also states that participants are free to stop the interview at any point if they wish.

The information sheet will also state that “The only occasion when confidentiality may be broken is if you disclose information which suggests that you pose a risk to yourself or others (including unsafe practice). If this situation arises then this will be discussed with you and may need to be discussed with a more senior member of the team.”

C.16 Will individual research participants receive any payments, fees, reimbursement of expenses or any other incentives or benefits for taking part in this research?

☐ Yes    ☑ No

If Yes, please describe the amount, number and size of incentives and on what basis this was decided.

RISKS OF THE STUDY

C.17 What are the potential benefits and/or risks for research participants in both the short and medium-term?

The information sheet highlights potential risks and benefits:

“Whilst there are no immediate benefits for those people participating in the project, it is hoped that this service evaluation project will give you the opportunity to talk about your experiences of delivering FBT which will hopefully increase understanding of how FBT is being delivered across the service so that recommendations can be made.

The service evaluation project may also help to maximise the use of FBT within the service as the themes identified may help to identify common factors that clinicians feel contributes to continuation/early discontinuation of FBT. Again, from this information,
recommendations may be made to the service.”

“There are two possible disadvantages to taking part. One may be giving up time for the interview, however, hopefully, the possible benefits of taking part will outweigh this. The second is that participants may feel concerned about being honest due to fear of negative consequences. Your responses will be kept confidential and you will not be identifiable from any quotations used. Any negative themes regarding how FBT is being delivered in the service will hopefully increase understanding and will likely be incorporated into improving the delivery of FBT across the service.”

C.18 Does the research involve any risks to the researchers themselves, or people not directly involved in the research? *Eg lone working* 36

☐ Yes ☑ No

*If yes, please describe:*

Is a risk assessment necessary for this research?

☑ Yes ☐ No

If yes, please include a copy of your risk assessment form with your application.

*NB: If you are unsure whether a risk assessment is required visit [http://ris.leeds.ac.uk/HealthAndSafetyAdvice](http://ris.leeds.ac.uk/HealthAndSafetyAdvice) or contact your Faculty Health and Safety Manager for advice.*

**RESEARCH DATA**

C.19 Explain what measures will be put in place to protect personal data. *Eg. anonymisation procedures, secure storage and coding of data.* Any potential for re-identification should be made clear to participants in advance. 37 Refer to [http://ris.leeds.ac.uk/ConfidentialityAnonymisation](http://ris.leeds.ac.uk/ConfidentialityAnonymisation) and [http://ris.leeds.ac.uk/ResearchDataManagement](http://ris.leeds.ac.uk/ResearchDataManagement) for guidance.

The information sheet states “Should you wish to take part, the project’s copy of the signed consent form will be stored in a locked draw/cabinet in the team office at the Reginald Centre (where the project is being carried out). Written notes taken in the interview will be anonymised so that they do not contain any identifiable information. These notes will be assigned a code known only to Lucy Siena so that you name is not matched to the interview notes. The code is required only in case you wish to withdraw your data (within 1 week of the interview). All notes will be kept confidential and stored in a locked draw or cabinet (separate to your consent form). The only occasion when confidentiality may be broken is if you disclose information which suggests that you pose a risk to yourself or others (including unsafe practice). If this situation arises then this will be discussed with you and may need to be discussed with a more senior member of the team.”
and “Some of your responses and words may be used within the final report to illustrate points, however, these quotations will be anonymised and you will not be identified or identifiable in the report that results from the research.”

C.20 How will you make your research data available to others in line with: the University’s, funding bodies’ and publishers’ policies on making the results of publically funded research publically available. Explain the extent to which anonymity will be maintained. (max 200 words) Refer to http://ris.leeds.ac.uk/ConfidentialityAnonymisation and http://ris.leeds.ac.uk/ResearchDataManagement for guidance.

Data will not be made publicly available. The information sheet states that data may be made available for relevant future research upon reasonable request to the research supervisor.

C.21 Will the research involve any of the following activities at any stage (including identification of potential research participants)? (Tick as appropriate)

- Examination of personal records by those who would not normally have access
- Access to research data on individuals by people from outside the research team
- Electronic surveys, please specify survey tool:
  ________________________________ (further guidance)
- Other electronic transfer of data
- Use of personal addresses, postcodes, faxes, e-mails or telephone numbers
- Use of audio/visual recording devices (NB this should usually be mentioned in the information for participants)
- FLASH memory or other portable storage devices

Storage of personal data on, or including, any of the following:

- University approved cloud computing services (Microsoft Office 365 for email (Exchange online) and Microsoft OneDrive for Business)
- Other cloud computing services
てくれる

C.22 How do you intend to share the research data? (Indicate with an ‘X) Refer to http://library.leeds.ac.uk/research-data-deposit for guidance.

☐ Exporting data outside the European Union
☐ Sharing data with other organisations
☐ Publication of direct quotations from respondents
☐ Publication of data that might allow identification of individuals to be identified
☐ Submitting to a journal to support a publication
☐ Depositing in a self-archiving system or an institutional repository
☐ Dissemination via a project or institutional website
☐ Informal peer-to-peer exchange
☐ Depositing in a specialist data centre or archive
☐ Other, please state: _____________________________________________.
☐ No plans to report or disseminate the data

C.23 How do you intend to report and disseminate the results of the study? (Indicate with an ‘X) Refer to http://ris.leeds.ac.uk/ResearchDissemination and http://ris.leeds.ac.uk/Publication for guidance.

☑ Conference presentation
☑ **Peer reviewed journals**
☐ Publication as an eThesis in the Institutional repository
☑ **Publication on website**
☑ Other publication or report, please state: _Internal report
Submission to regulatory authorities
☐ Other, please state: ____________________________________________.
☐ No plans to report or disseminate the results

C.24 For how long will data from the study be stored? Please explain why this length of time has been chosen.\(^{38}\) Refer to the RCUK Common Principles on Data Policy and http://ris.leeds.ac.uk/info/71/good_research_practice/106/research_data_guidance/5. Students: It would be reasonable to retain data for at least 2 years after publication or three years after the end of data collection, whichever is longer.

___3____ years, ___0____ months

CONFLICTS OF INTEREST

C.25 Will any of the researchers or their institutions receive any other benefits or incentives for taking part in this research over and above normal salary or the costs of undertaking the research?\(^ {39}\)

☐ Yes ☑ No

If yes, indicate how much and on what basis this has been decided

___________________________________________________________________________

C.26 Is there scope for any other conflict of interest?\(^ {40}\) For example, could the research findings affect any ongoing relationship between any of the individuals or organisations involved and the researcher(s)? Will the research funder have control of publication of research findings? Refer to http://ris.leeds.ac.uk/ConflictsOfInterest.

☑ Yes ☑ No

If so, please describe this potential conflict of interest, and outline what measures will be taken to address any ethical issues that might arise from the research.

The team/service will be informed of the results of the service evaluation project and there is a possibility that the analysis will include negative as well as positive themes. The team/service is aware of this and understanding of the negative themes will likely be incorporated into improving the delivery of FBT across the service.

C.27 Does the research involve external funding? (Tick as appropriate)

☐ Yes ☑ No

If yes, what is the source of this funding?

___________________________________________________________________________
NB: If this research will be financially supported by the US Department of Health and Human Services or any of its divisions, agencies or programmes please ensure the additional funder requirements are complied with. Further guidance is available at http://ris.leeds.ac.uk/FWAcompliance and you may also contact your FROI0 for advice.
PART D: Declarations

Declaration by Chief Investigators

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to abide by the University's ethical and health & safety guidelines, and the ethical principles underlying good practice guidelines appropriate to my discipline.

3. If the research is approved I undertake to adhere to the study protocol, the terms of this application and any conditions set out by the Research Ethics Committee.

4. I undertake to seek an ethical opinion from the REC before implementing substantial amendments to the protocol.

5. I undertake to submit progress reports if required.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the University’s Data Protection Controller (further information available via http://ris.leeds.ac.uk/ResearchDataManagement).

7. I understand that research records/ data may be subject to inspection for audit purposes if required in future.

8. I understand that personal data about me as a researcher in this application will be held by the relevant RECs and that this will be managed according to the principles established in the Data Protection Act.

9. I understand that the Ethics Committee may choose to audit this project at any point after approval.

Sharing information for training purposes: Optional – please tick as appropriate:

I would be content for members of other Research Ethics Committees to have access to the information in the application in confidence for training purposes. All personal identifiers and references to researchers, funders and research units would be removed.

Principal Investigator

Signature of Principal Investigator: M. Siena (This needs to be an actual signature rather than just typed. Electronic signatures are acceptable)

Print name: Lucy Siena Date: (dd/mm/yyyy): 03/12/18
Supervisor of student research: I have read, edited and agree with the form above.

Supervisor’s signature: .... .................................................... (This needs to be an actual signature rather than just typed. Electronic signatures are acceptable)

Print name: .......Dr Gary Latchford.............................................. Date: 09/12/18
..........................................................................................

Please submit your form by email to researchethics@leeds.ac.uk or if you are in the Faculty of Medicine and Health FMHUniEthics@leeds.ac.uk. Remember to include any supporting material such as your participant information sheet, consent form, interview questions and recruitment material with your application.
To help speed up the review of your application:

- Answer the questions in plain English, avoid using overly technical terms and acronyms not in common use.

- Answer all the questions on the form, including those with several parts (refer to the guidance if you’re not sure how to answer a question or how much detail is required).

- Include any relevant supplementary materials such as
  - Recruitment material (posters, emails etc)
  - Sample participant information sheet
  - Sample consent form. Include different versions for different groups of participants eg for children and adults, clearly indicating which is which.
  - Signed risk assessment (If you are unsure whether a risk assessment is required visit http://ris.leeds.ac.uk/HealthAndSafetyAdvice or contact your Faculty Health and Safety Manager for advice.).

   Remember to include use version control and meaningful file names for the documents.

- If you are not going to be using participant information sheets or consent forms explain why not and how informed consent will be otherwise obtained.

- If you are a student it is essential that you discuss your application with your supervisor.

- Submit a signed copy of the application, preferably electronically. Students’ applications need to be signed by their supervisors as well.
Appendix 2: Participant information sheet.

Participant Information Sheet

Maximising the utility of Family Based Treatment (FBT) – Identifying the Factors that Impact Upon the Outcome

You are invited to take part in a service evaluation project. Before you decide whether to take part or not, it is important that you understand why the service evaluation is being carried out and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. If you have any questions, if anything is not clear or if you would like any further information, please speak with Lucy Siena or Julie Franklin (contact details at the bottom of this page).

What is the purpose of the project?
The aims of this service evaluation project are:

- To provide staff with the opportunity to reflect upon their experiences of delivering FBT to increase understanding of how FBT is being delivered within the service.
- To investigate what factors clinicians think impacts on early discontinuation of FBT.
- To investigate what factors clinicians think enables families to remain in FBT/complete FBT.
- To consider all this information with a view to providing recommendations to the service.
- To use the findings to help determine which families FBT may be more suitable for (this may help at the assessment stage).

Why have I been chosen?
You have been chosen to take part as you are one of the clinicians currently delivering or who have previously delivered FBT within the service. All clinicians who are currently delivering or who have previously delivered FBT within the service will be given the opportunity to take part.

What do I have to do if I take part?
The service evaluation will involve one 1:1 interview with Lucy Siena, lasting approximately 45 minutes – 1 hour. The interviews will take place at the Redinald Centre.

Questions in the interview will be open ended, giving you the opportunity to talk in detail about your experiences of delivering FBT. You will also be asked about what factors you think impacts upon the decision to discontinue FBT as an intervention for some families and about what you think increases the likelihood of families remaining in treatment and benefiting from it. We ask that you respond to questions openly and honestly.

Why are these questions important/what are the benefits of taking part?
Whilst there are no immediate benefits for those people participating in the project, it is hoped that this service evaluation project will give you the opportunity to talk about and reflect upon your experiences of delivering FBT. This will hopefully increase understanding of how FBT is
being delivered and the understanding of the impact of introducing a new therapeutic modality into the service.

The service evaluation project may also help to maximise the use of FBT within the service as the themes identified may help to identify common factors that clinician’s feel contributes to continuation/early discontinuation of FBT. The wider benefits include improving outcomes for families and continued service improvement as recommendations may be made.

What are the possible disadvantages and risks of taking part?

There are two possible disadvantages to taking part. One may be giving up time for the interview, however, hopefully, the possible benefits of taking part will outweigh this. The second is that participants may feel concerned about being honest due to fear of negative consequences. Your responses will be kept confidential and you will not be identifiable from any quotations used. Any negative themes regarding how FBT is being delivered in the service will hopefully increase understanding and will likely be incorporated into improving the delivery of FBT across the service.

Do I have to take part?

Participation in the service evaluation project is voluntary and should you not wish to take part, there will be no consequences.

If you decide to take part, you will be given this information sheet and will be asked to sign a consent form which you will also be given a copy of. You can withdraw at any point (up until 1 week after your interview when data will have been incorporated into the analysis) without having to provide a reason and without any consequences. It will not be possible to withdraw data after this point as it will have been incorporated into the analysis. Should you not wish to answer any question within the interview, you are free to decline. You are also free to stop the interview at any point if you wish to.

Withdrawing

If you do wish to withdraw before, during or after your interview, please contact Lucy Siena at ps11mls@leeds.ac.uk Any data provided before withdrawal will be discarded (notes will be disposed of in confidential waste).

Will my taking part in this project be kept confidential/ What will happen to the results of the research project?

Should you wish to take part, the project’s copy of the signed consent form will be stored in a locked draw/cabinet in the team office at the Reginald Centre (where the project is being carried out). Written notes taken in the interview will be anonymised so that they do not contain any identifiable information. These notes will be assigned a code known only to Lucy Siena so that you name is not matched to the interview notes. The code is required only in case you wish to withdraw your data (within 1 week of the interview). All notes will be kept confidential and stored in a locked draw or cabinet (separate to your consent form). The only occasion when confidentiality may be broken is if you disclose information which suggests that you pose a risk to yourself or others (including unsafe practice). If this situation arises then this will be discussed with you and may need to be discussed with a more senior member of the team.

Data will be stored for up to 3 years (in line with information governance requirements) and may be made available for relevant future research upon reasonable request to the research supervisor.

Last updated 04/02/2019
Some of your responses and words may be used within the final report to illustrate points, however, these quotations will be anonymised and you will not be identified or identifiable in the report that results from the research. This report will be made available to you and anyone within the team after completion (November 2019 at the latest) and may be disseminated in a team meeting. The report may also be published in an academic journal or presented at a relevant conference.

Who is organising/ funding the research?

This service evaluation project is commissioned by Leeds Community Healthcare NHS Trust and supervised by Dr Julie Franklin.

Ethical approval has been sought from the School of Medicine Research Ethics Committee (SHREC project number DClinREC18-011).

Contact for further information

If you have any questions or concerns, please contact:

Lucy Siena: ps11mls@leeds.ac.uk
Julie Franklin: julie.franklin@nhs.net (0113 843 4317)

Leeds Children and Young People’s Eating Disorder Service
The Reginald Centre
Chapeltown Road
Leeds
LS7 3EX

Dr Gary Latchford: g.latchford@leeds.ac.uk

Programme in Clinical Psychology
Leeds Institute of Health Sciences
Level 10, Worsley Building
Clarendon Road
Leeds, LS2 9NL

Thank you for taking the time to read this information sheet.

<table>
<thead>
<tr>
<th>Maximising the utility of Family Based Treatment – Identifying the Factors that Impact Upon the Outcome</th>
<th>Document type</th>
<th>Version</th>
<th>Date</th>
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<tbody>
<tr>
<td>Information sheet for participants</td>
<td></td>
<td>2</td>
<td>23/12/18</td>
</tr>
</tbody>
</table>
Appendix 3: Participant consent form.

Consent to take part in “Maximising the utility of Family Based Treatment – Identifying the Factors that Impact Upon the Outcome”

I confirm that I have read and understand the information sheet dated 28/11/18 explaining the above service evaluation project and I have had the opportunity to ask questions about the project.

I understand that my participation is voluntary and that I am free to withdraw at any point up to 1 week after the interview (when data will be incorporated into the analysis) without giving any reason and without there being any negative consequences. In addition, I understand that should I not wish to answer any particular question or questions, I am free to decline.

I understand that any data provided before withdrawal will be discarded (notes will be disposed of in confidential waste). If you do wish to withdraw your data, please contact Lucy Siena at ps11mls@leeds.ac.uk.

I give permission for members of the project team to have access to my anonymised responses. I understand that my name will not be linked with the project materials (i.e. notes from the interview), and I will not be identified or identifiable in the report or reports that result from the project.

I understand that my responses or words may be used in publications, reports, web pages, at conferences and in other outputs, but that responses will be anonymised, and I will not be identifiable from these words.

I agree for the data collected from me to be stored for up to 3 years (in line with Information Governance requirements) and used in relevant future service evaluation (in an anonymised form).

I agree to take part in the above service evaluation and will inform the lead researcher should my contact details change during the project and, if necessary, afterwards.

Name of participant

Participant’s signature

Date

Name of lead researcher Lucy Siena

Signature

Date*

*To be signed and dated in the presence of the participant.

Once this has been signed by all parties the participant should receive a copy of the signed and dated participant consent form, the letter/ pre-written script/ information sheet and any other written information provided to the participants. A copy of the signed and dated consent form should be kept with the project’s main documents which must be kept in a secure location.

Maximising the utility of Family Based Treatment – Identifying the Factors that Impact Upon the Outcome

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Appendix 4: Interview Schedule.
Questions in bold are main interview questions, questions underneath were possible follow up questions which were guided by the conversation.

1. **Please can you tell me about your experience of delivering FBT? (positives and negatives)**
   Possible probe/follow up questions:
   - What do you think of FBT?
   - Do you feel as though there is anything missing in FBT that people would benefit from?
   - Has delivering FBT changed your clinical practice? If so, how?
   - How does FBT compare to other treatments you have delivered within this clinical population?
   - Are you having supervision? How often? Is it beneficial?
   - Do you use any other resources do you use to support your delivery of FBT (resources from Stamford – hugging the iceberg, aliens on mars? If so, what? If not, what are the barriers (not knowing, stored in dropbox)?
   - Do you use the manual? If yes – what is useful about it? If no - why not/what are the barriers?
   - Would you say you stick to the manual/session plans? Why/why not?
   - Do you draw from any other interventions/models as well as using the manual?
   - Are you using eating plans with the families?
   - Is there anything else you want to tell me about your experience of delivering FBT that we haven’t already discussed?

2. **What do you think impacts on the decision to discontinue FBT earlier than planned for some individuals?**
   Possible probe/follow up questions:
   - Is there anything else that impacts on a decision to discontinue FBT?
   - Do you think that you/the team have any influence over these factors? If yes -which ones, how could you influence/what could help. If no – why not/what are the barriers?

3. **What do you think increases the likelihood of a family remaining in treatment/completing treatment?)**
   Possible probe/follow up questions:
   - What do you think it is it about these families that makes them more likely to remain in treatment?
   - Do you think there are any similarities between the individuals/families that remain in treatment?
- What do you think it is about the individual that makes them more likely to remain in treatment?
- Do you think there is anything about the clinician/service that makes a family more likely to remain in treatment?

Anything else you want to comment on/not been asked about already?
Exploring the Implementation of Family Based Treatment (FBT) in Leeds Children and Young People’s Eating Disorder Service

Claire Randall & Lucy Sien - Trainee Clinical Psychologists
Leeds Children and Young People’s Eating Disorder Service

Background

The Leeds Children and Young People’s Eating Disorder Service was formed in November 2016. Clinicians were trained in FBT in response to updated local guidance (2017). FBT is a manualised treatment for young people with Anorexia Nervosa (AN) and Bulimia Nervosa (BN). The young person’s key elements of family therapy and the role of the carers is important across the three phases of treatment.

Phase 1: Involves initial contact with the aim of ensuring informed consent and initiating a service delivery plan. Therapy focuses on the eating disorder and reviews a family meal where the patient observed family interactions.

Phase 2: Through family coaching the adolescents in weight refeeding has been achieved.

Phase 3: Establishing a healthy weight. The focus remains on establishing good family relationships, increasing autonomy in the young person and reducing the prevalence of bulimia.

Last year, of 130 patients, evaluated this treatment approach. Family demonstrated that 75% of young persons achieved a significant change in weight for height (80%); and a “normal” score on the Eating Disorder Examination measure. Furthermore, 76% no longer met the DSM IV criteria for AN in that weight, having completed the intervention.

Present Study

This study was commissioned by the Leeds D.Clin.Psychol Programme, 2019. This study was conducted in four parts: (1) The first part involved qualitative data to understand the effectiveness of FBT. The second part gathered quantitative information by interviewing clinicians who were actively involved in delivering FBT in the service. Both parts of the study were carried out with a view to suggest recommendations to the service.

Study 1

1. Aim

To determine the effectiveness of FBT for young people with Anorexia Nervosa (AN) and Bulimia Nervosa (BN) in the Eating Disorder Service (EDS) of the Leeds Children and Young People’s Eating Disorder Service (CP)

2. Method

Participants (130 patients) were included in the study. 130 families were included in the intervention. The families were divided into three stages of treatment. The first stage was the initial phase where the families were introduced to the principles of FBT. The second stage was the family coaching phase where the families were coached in weight refeeding. The third stage was the establishment of a healthy weight where the families were encouraged to maintain a healthy weight and decrease the prevalence of bulimia.

3. Results

Young persons who completed FBT showed significant improvement in weight loss over the intervention (short-term). At the end of the treatment, 80% of young persons achieved a healthy weight. The families were encouraged to maintain a healthy weight and decrease the prevalence of bulimia.

4. Discussion

For those who completed the intervention, FBT appears to be effective in supporting young people to weight normal and maintain healthy eating. It is important to note that the small sample size and the findings need to be replicated in a larger study.

Recommendations

1. Improve the treatment model when more families have completed FBT

2. The service now implementing a pathway where cases are reviewed every 4-6 weeks to ensure continuity and enhance fidelity to FBT. It may be helpful that within this pathway the young person’s age, weight and BMI are reviewed at each contact. The interventions are consistent across the phases of treatment and the pathways are consistent.

3. Improved training for families with written information regarding the effectiveness of FBT in order to facilitate early engagement to the treatment.

Appendix 5: Poster presented at University of Leeds Conference.