Title: Assessing the impact of First Episode Rapid Early Intervention for Eating Disorders (FREED) on duration of untreated eating disorder: A multi-centre quasi-experimental study

Running title: The impact of FREED on duration of untreated ED

Authors:

Flynn, M.[1], Austin, A.[1], Lang, K.[1] , Allen, K. L.[1,2], Bassi, R.[2], Brady, G. [7], Brown, A.[2], Connan, F. [7], Franklin-Smith, M.[4], Glennon, D.[2], Grant, N.[2], Jones, W. R.[4], Kali, K. [7], Koskina, A.[2], Mahony, K. [5], Mountford, V. A.[1,2,3], Nunes, N. [7], Schelhase, M.[4], Serpell, L.[5,6] & Schmidt, U.[1,2]

Corresponding author: Ulrike Schmidt, Section of Eating Disorders, PO Box 59, Institute of Psychiatry, Psychology and Neuroscience, De Crespigny Park, London, SE5 8AF, email address: ulrike.schmidt@kcl.ac.uk

Affiliations:

1: King's College London, Institute of Psychiatry, Psychology and Neuroscience, London, UK

2: South London and Maudsley NHS Foundation Trust, London, UK

3: Maudsley Health, Abu Dhabi, UAE

4: Leeds and York Partnership NHS Foundation Trust, Leeds, UK

5: North East London NHS Foundation Trust, London, UK

6: University College London, Division of Psychology and Language Sciences, London, UK

7: Central and North West London NHS Foundation Trust, London, UK

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Title: Assessing the impact of First Episode Rapid Early Intervention for Eating Disorders (FREED) on duration of untreated eating disorder: A multi-centre quasi-experimental study

Abstract:

Background: Duration of untreated eating disorder (DUED), i.e., the time between illness onset and start of first evidence-based treatment, is a key outcome for early intervention. Internationally, reported DUED ranges from 2.5 to 6 years for different eating disorders (EDs). To shorten DUED, we developed FREED (First Episode Rapid Early Intervention for EDs), a service model and care pathway for emerging adults with EDs. Here, we assess the impact of FREED on DUED in a multi-centre study using a quasi-experimental design.

Methods: 278 patients aged 16-25, with first episode illness of less than 3 years duration, were recruited from specialist ED services and offered treatment via FREED. These were compared to 224 patients, of similar age and illness duration, seen previously in participating services (treatment as usual; TAU) on DUED, waiting times, and treatment uptake.

Results: FREED patients had significantly shorter DUED and waiting times than TAU patients. On average, DUED was reduced by ~4 months when systemic delays were minimal. Further, 97.8% of FREED patients took up treatment, versus 75.4% of TAU.

Discussion: Findings indicate that FREED significantly improves access to treatment for emerging adults with first episode ED. FREED may reduce distress, prevent deterioration and facilitate recovery.

Highlights:

- This study is a large-scale replication of an earlier single-centre pilot study of FREED. Findings indicate that, as in the pilot study, FREED significantly reduces DUED and is associated with significantly shorter wait times for both assessment and treatment when implemented at scale.
- Differences between groups were more pronounced when systemic delays were minimal.
- The proportion of FREED patients taking up treatment was significantly higher than in TAU, suggesting that a shorter interval between help-seeking from primary care and an offer of specialist assessment/treatment has clear down-stream benefits.

List of Abbreviations:

AN: Anorexia nervosa

BN: Bulimia nervosa

BED: Binge eating disorder

CNWL: Central and North West London NHS Foundation Trust

DSM-5: Diagnostic and Statistical Manual of Mental Disorders, 5th Edition

DUED: Duration of untreated eating disorder

DUSC: Duration untreated to specialist care

ED: Eating Disorder

FREED: First Episode Rapid Early Intervention for Eating Disorders

LYPFT: Leeds and York Partnership NHS Foundation Trust

NELFT: North East London NHS Foundation Trust

NICE: The National Institute for Health and Care Excellence

OSFED: Other specified feeding or eating disorder

SLaM: South London and Maudsley NHS Foundation Trust

TAU: Treatment as usual

Keywords: eating disorders, anorexia nervosa, bulimia nervosa, binge eating disorder, early intervention, duration of untreated illness, FREED

Introduction

Early intervention and associated stage models of disease have led to improved outcomes and higher survival rates in many potentially chronic or life-threatening disorders, from cancer to cardiovascular disease. Early intervention has been defined as early detection of disease followed by stage-specific or proportionate intervention, for as long as necessary and effective (McGorry, Ratheesh, & O'Donoghue, 2018). In relation to mental health, these ideas have been most rigorously adopted and researched in the area of psychosis (Correll et al., 2018), for which early intervention services are now established in many countries (McGorry & Mei, 2018). Early intervention services for other mental disorders, including eating disorders (EDs), are also emerging (Richards, Austin, Allen, & Schmidt, 2019).

Active attempts to reduce the duration of untreated illness have been a key strategy for promoting favourable long-term outcomes for individuals with early stage illness (Oliver et al., 2018; Penttila, Jaaskelainen, Hirvonen, Isohanni, & Miettunen, 2014; Sullivan et al., 2019). In doing so, early intervention aims to prevent neuroprogression, i.e., neurobiological changes associated with illness symptoms which unfavourably affect illness trajectory (Gama, Kunz, Magalhaes, & Kapczinski, 2013; Moylan, Maes, Wray, & Berk, 2013).

In EDs there is growing bio-behavioural evidence that the illness changes over time, with maladaptive eating and weight control behaviours becoming gradually more automatic and entrenched (Berner & Marsh, 2014; Dalton, Foerde, et al., 2020; Fladung et al., 2010; Fladung, Schulze, Schöll, Bauer, & Grön, 2013; O'Hara, Campbell, & Schmidt, 2015; Shott et al., 2012; Steinglass & Walsh, 2016; Werthmann et al., 2019). Consistent with these findings, many (though not all) clinical studies suggest that response to treatment is greatest in the early stages of the illness (i.e., within the first 3 years from ED onset), and diminishes the longer the disorder persists (Ambwani et al., 2020; Treasure, Stein, & Maguire, 2015).

Similarly, studies show that, during early stage ED, longer illness duration is associated with greater social and occupational impairment and psychological distress (Davidsen, Hoyt, Poulson, Waaddegaard & Lau, 2017; de Vos, Radstaak, Bohlmeijer, & Westerhof, 2018). As such, a lack of or delay in access to effective treatment during the early stages of ED may negatively impact the chance of recovery, facilitate chronicity, jeopardise social and occupational attainment and unnecessarily prolong suffering.

We recently completed a systematic review of the duration of untreated eating disorder (DUED), i.e., the time from onset of symptoms to the start of evidence-based treatment, in studies of first episode ED. Across studies, the pooled average DUED was between 2 and 3 years for anorexia nervosa (AN), and 4.4 and 5.6 years for bulimia nervosa (BN) and binge eating disorder (BED) respectively (Austin et al., 2020). This suggests that, internationally, DUED for different diagnoses is lengthy, with significant room for improvement. If successful strategies for early intervention are to be developed, a clear understanding of DUED, pathways into care and barriers to accessing prompt evidence-based specialist treatments during a first episode of an ED are necessary.

The time from ED onset to start of evidence based treatment can broadly be divided into two stages (Birchwood et al., 2013). During the first stage, delays are driven by patient-related factors; here, an individual experiences symptoms but doesn't recognise that they have a problem or is not ready to seek help. In the second stage, an individual has sought help and is waiting for treatment, and service-level delays prolong the period of untreated illness. Rigorous efforts to reduce the impact of service level delays on people with first episode EDs must strive to reduce both time from illness onset to first contact with specialist care (DUSC), and time from onset to start of evidence based treatment (i.e., DUED). To date, and to the best of our knowledge, only two small studies have assessed whether the introduction of an

early intervention service for EDs is able to reduce DUSC and/or DUED. One of these studies, the Psychenet study, aimed to reduce DUED in adolescents and adults with AN by implementing a public health intervention into the education/health care systems in the city of Hamburg, Germany (Gumz, Weigel, Wegscheider, Romer, & Lowe, 2018; Weigel et al., 2015). Psychenet was an ambitious and well-coordinated intervention, designed and championed by experts in ED care. The intervention aimed to facilitate early detection of AN, and promote timely help seeking. However, following the implementation of this complex intervention, neither DUED nor time to first specialist assessment were reduced. The mean DUED was 36.5 months (SD=68.2) before and 40.1 months (SD=89.4) after the implementation of the systemic public health intervention. The mean duration until first contact with the health care system was 25.0 months (SD=53.0) before and 32.8 months (SD=86.5) after the intervention.

The second study assessed the impact of the First Episode Rapid Early Intervention for EDs (FREED) service model and care package, designed for 16 to 25-year-olds presenting with a first episode ED of less than 3 years duration (Schmidt, Brown, McClelland, Glennon, & Mountford, 2016). FREED provides highly coordinated person-centred care which is tailored to the needs of emerging adults. Reducing DUED by encouraging early referral from primary care and reducing waiting times within specialist ED services is a central focus for FREED. The FREED model was evaluated in a single centre pilot study using a quasi-experimental pre-post design (Brown et al., 2018; McClelland et al., 2018). The pilot compared outcomes for 56 FREED patients to those of 86 treatment as usual (TAU) controls, who had previously been seen in the service and were similar in age and illness duration. Overall, FREED patients had non-significantly shorter DUSC and DUED than TAU patients: 15.7 (SD 10.04) and 16.4 months (SD 10.1) vs 16.2 (SD 10.6) and 19.1 months (SD 11.7) for DUSC and DUED, respectively. However, those patients who received FREED under optimal

circumstances (i.e., with minimal National Health Service gatekeeping), had significantly shorter DUED (13.0 months) than controls. Relative to TAU, FREED patients all waited significantly less time for both assessment and treatment, and had significantly better treatment uptake (Brown et al., 2018). Importantly, FREED patients also showed significantly greater clinical improvement up to 2 years later and need for hospital admissions was reduced (Fukutomi et al., 2020; McClelland et al., 2018).

The divergent findings from these two studies highlight that reducing DUED is not straight-forward. As such, here, we wanted to assess the impact of FREED on DUED, DUSC, waiting times from referral to specialist assessment and start of evidence-based treatment, and treatment uptake in a larger multi-centre study (FREED-Up; Schmidt et al., 2020; unpublished report). Clinical outcomes from the FREED-Up study will be reported elsewhere (Austin et al., *submitted).*

Methods

Ethical approval for the study was granted by the Camberwell St Giles Research Ethics Committee (ref: 16/LO/1882) and NHS Health Research Authority.

Design

The study used a quasi-experimental pre-post design, comparing patients before and after implementation of FREED in participating services, to determine how FREED compared with TAU in relation to DUED and service-related process variables (i.e., waiting times and treatment uptake). To reduce the potential for various environmental, ecological and systemic factors to bias participant assignments to the two conditions, FREED and TAU patients were drawn from the same population (i.e. they were patients from the same catchment area) and, to ensure that external conditions affecting patient recruitment for TAU were as similar as possible to FREED, the TAU period was immediately prior to the introduction of FREED.

Participants

FREED-Up Cohort

FREED-Up participants were recruited from consecutive referrals to four large specialist NHS ED outpatient services. These were the services at the South London and Maudsley NHS Foundation Trust (SLaM), the Central and North West London NHS Foundation Trust (CNWL), the North East London NHS Foundation Trust (NELFT) and the Leeds and York Partnership NHS Foundation Trust (LYPFT). Three of the participating services see patients aged 18 and above. The fourth (NELFT) is a life span service; here, patients aged ≥16 years were included in FREED. Collectively, the participating services covered a catchment population of approximately 7 million people from urban, sub-urban and rural areas in England.

Eligible patients were aged 16-25, had a primary DSM-5 ED diagnosis and an ED illness duration of ≤ 3 years. Exclusion criteria were: (1) need for immediate inpatient admission (using guidance from the National Institute for Health and Care Excellence [NICE; 2017] to inform decision-making), (2) the presence of a comorbid physical/mental disorder requiring priority treatment (e.g., active psychosis), and (3) severe learning disability or English language difficulty that would preclude completion of study questionnaires.

Treatment as usual (TAU) cohort

We conducted an audit of electronic patient records was conducted to identify consecutive referrals to participating services over a 2 year period prior to the introduction of FREED to identify patients of comparable age and illness duration (i.e., aged 16/18-25 years with illness duration <3 years) for inclusion in the TAU cohort. Information regarding ED onset and illness duration was obtained from clinical assessment letters. Those with illness duration ≤ 3

years were included in the comparison cohort. Data relating to DUED and wait times for assessment and treatment were extracted for the evaluation of process outcomes.

Procedures

Clinical Procedures

The FREED service model/care pathway and its implementation are described elsewhere (Allen et al., 2020; Brown et al., 2018; Schmidt et al., 2016). In brief, all referrals for individuals aged 16-25 years are screened by telephone within 48 hours of referral by an ED clinician with the role of 'FREED champion'. Each screening call takes approximately 15 minutes to complete. Patients that are potentially eligible for FREED are immediately booked into the next available assessment (aiming for < 2 weeks from referral date). The standard ED assessment protocol used in each service is adapted for FREED clinical assessments. Assessments are biopsychosocial, person-centred, and consider the young person within their family and social context, focusing on their needs, priorities and strengths. Where possible, family members and close others join for part of the assessment. During assessment, attention is paid to the patient's use of social media and health-related apps and emphasis is placed on providing tailored psychoeducation, highlighting the malleability of ED related changes to brain, body and behaviour during the early stages of the illness. Crucially, initial goals for treatment are collaboratively identified at assessment and linked to the psychoeducation provided. Following this, FREED eligible individuals are rapidly allocated to a therapist (aiming for < 2 weeks from assessment) to start an evidence-based, stage-appropriate, NICE-recommended psychological treatment. Treatment duration is typically 20 to 30 sessions, and sessions with family members/carers are encouraged. Similarly, early involvement of the team dietician is also encouraged. Where relevant, management of transitions (e.g., to university or from child and adolescent mental health services) is considered to minimise their impact on treatment.

Research Procedures

Patients eligible for treatment via the FREED service model/pathway were invited to take part in the study after their clinical assessment. All participants were required to give their written, informed consent. Following this, they took part in a semi-structured interview with a researcher focusing on illness onset and duration. Demographic data were obtained from baseline questionnaire measures collected as part of the study's longitudinal assessment of clinical outcomes. Longitudinal clinical outcomes will be reported elsewhere (Austin et al., *submitted).* Data relating to each patient's journey through the service, including dates for referral, screening, assessment and start of treatment, were recorded by the FREED champion at each site. For patients in the TAU cohort, equivalent referral, assessment and treatment data were extracted from clinical notes by the study researchers.

Outcomes

Demographics

Socio-demographic data of FREED patients were obtained at baseline and for TAU patients extracted from their electronic patient records.

ED onset, duration until specialist service contact (DUSC) and duration of untreated eating disorder (DUED)

A structured onset interview, including variables from the Eating Disorder Diagnostic Scale (Stice, Telch, & Rizvi, 2000) and the Eating Disorder Examination (Cooper & Fairburn, 1987), was used, together with a life chart to accurately ascertain the onset, duration, frequency and severity of ED symptoms in FREED participants (Brown & Harris, 1989) . This chart allows the young person to use 'anchor points' (e.g., birthdays, starting university, etc.) to help orientate them to the time of symptom onset and change. Onset was defined as the time at which symptoms reached a degree of severity that met DSM-5 criteria for an ED.

Assessing clinicians were also asked to determine the time of ED onset and this was recorded in the assessment notes.

For TAU participants, ED onset was determined using clinical assessment letters. Assessment letters for a subset of FREED patients were also reviewed by an independent rater, blind to interview and clinician determined onset. The blind rater used information from clinical assessment letters to determine ED onset. Systematic differences between interview-determined and assessment letter determined onset were examined to assess the reliability of this substitute for interview determined onset.

DUSC was defined as the length of time (in months) between ED onset and the date of specialist clinical assessment. DUED was defined as the length of time (in months) between ED onset and start of evidence-based treatment.

Waiting Times

Wait times for assessment and treatment were defined as the time period (in weeks) from the date the referral was received by the service to the date the patient *attended* a) their clinical assessment and b) their first treatment session.

Treatment Uptake

Treatment uptake was defined as attending at least one treatment session following clinical assessment.

Analysis

Statistical analyses were performed using IBM® SPSS® software (Version 26).

Overall, our analyses followed the recommendations of the Child Outcome Research Consortium (CORC) for service data (http://www.corc.uk.net/media/1533/fupsleaflet.pdf). The CORC suggestion is to provide accessible descriptive analyses first and foremost, and only undertake statistical tests where there is a clear reason to do so.

With this in mind, we firstly present descriptive data for demographic and key clinical features by group. We then assess the relative impact of implementing FREED on DUSC, DUED and service related outcomes (i.e., waiting times and treatment uptake) by comparing the FREED group with the TAU group using t-tests, ANOVAs and, where appropriate, present Kaplan Meyer survival curves with associated log rank tests. Where a significant difference between groups is observed, Hedge's *g*, which provides a measure of effect size weighted according to the relative size of each sample, is reported. Generally, effect sizes of 0.2, 0.5 and 0.8 are considered small, moderate, and large, respectively.

Results

Participant flow and sample characteristics

Participant flow is shown in Figure 1. FREED participants (n=278) were recruited from participating outpatient ED services (SLaM, *n*=118; CNWL, *n*=86; NELFT, *n*=34; LYPFT; *n*=40). The TAU comparison group consisted of 224 patients (SLaM, *n*=84; CNWL, *n*=76; NELFT, *n*=44; LYPFT, *n*=20).

INSERT FIGURE 1 HERE.

Within the FREED group, 56.5% (157/278) of patients received the FREED intervention under optimal conditions. Optimally delivered FREED was defined as receiving immediate specialist evidence-based assessment and treatment straight upon help-seeking without delays or detours (e.g., consecutive involvement of or direct transfer/transition between different services). The remaining 121 patients were affected by at least one of the following: NHS gate keeping delays (e.g., delays receiving funding for assessment and/or treatment; *n*=55), involvement of different services (e.g., transition between eating disorder services ED or between general community mental health services and specialist ED care, *n*=67), or patient driven delays (e.g., travel during university holidays; *n*=30).

Participant characteristics

Table 1 presents demographic and clinical characteristics for FREED and TAU patients.

INSERT TABLE 1 HERE.

DUSC and DUED

Table 2 shows the differences between FREED and TAU groups for mean DUSC and DUED (see Supplementary Table 1 for a breakdown of these data by diagnosis). There was no significant difference in DUSC following the introduction of FREED, even when FREED was delivered optimally. However, there was a significant reduction in DUED following the introduction of FREED. Follow-up comparisons delineated that for FREED patients where start of treatment was delayed (n=119), DUED remained unchanged despite the introduction of FREED (p=0.93). Conversely, when delivered under optimal conditions, FREED substantially reduced DUED, with FREED patients commencing specialist treatment 4 months earlier, on average, than TAU patients.

INSERT TABLE 2

Importantly, within the FREED model whilst assessment and start of treatment are separate, they are typically close together and the clinical assessment includes many components of a typical first treatment session. For example, during assessment clinicians encourage the person to take active steps towards symptom change and provide tailored psychoeducation. Therefore, the assessment date may reasonably be considered the start of treatment for FREED patients. If conceptualised in this way, the introduction of FREED further reduced DUED ($t(428)= -2.98$, $p< 0.05$, Hedge's $g =-0.30$), with FREED patients commencing treatment an average of 3.16 months earlier than TAU patients, and 4.87 months earlier when FREED is delivered under optimal conditions ($t(153)= -4.13$, $p<0.001$, Hedge's $g= -0.47$).

A two-way ANOVA assessing the effect of ED diagnosis on DUED for FREED and TAU groups revealed a main effect for diagnosis ($F(3,318)=4.27$, $p= 0.015$) however, there was no significant interaction between diagnosis and intervention type (FREED or TAU). As such, in both the FREED and the TAU groups there was significant variation in DUED by diagnosis, with patients with BN in both cohorts presenting with substantially longer DUED than those with other diagnoses.

Kaplan-Meier survival curves were constructed to illustrate the cumulative probability of start of treatment following onset of the ED. As shown in Figure 2, Kaplan-Meier survival curves revealed a significant difference in cumulative probability of starting treatment following onset of the ED after the introduction of FREED, particularly when this is delivered under optimal conditions (log-rank test $x^2= 11.86$, $df=1$, $p<0.001$).

INSERT FIGURE 2 HERE

In the FREED cohort, ED onset was assessed using the researcher led onset-interview. In addition, clinicians conducting clinical assessments also reported their independent estimates of ED onset. Paired samples t-tests were used to determine whether there were systematic differences between onset-interview determined DUED and clinician-determined DUED. Results indicated that clinician estimated DUED (M= 20.02 months, SD=10.91) was ~2 months longer than interview determined DUED (M= 17.85 months, SD=10.38), on average ($t(249)=6.95$, $p<0.01$), however, the effect size was small (Hedge's $g=0.20$).

In the TAU cohort, ED onset was determined by reviewing clinical assessment letters. To estimate the reliability of this substitute for interview reported DUED, clinical assessment letters for a subset of FREED patients ($n=100$) were reviewed by an independent rater, blind to interview and clinician determined ED onset. The blind rater used information from clinical assessment letters to determine ED onset. A paired samples t-test indicated that ED

onset, and therefore DUED, did not vary depending on whether it was determined by interview or by assessment letter (*p=0.15).*

Waiting Times

Screening

The median wait time for FREED screening was 2.5 days and wait time to screening did not differ by site (p=0.285).

Assessment

Table 2 shows mean wait time from referral to specialist assessment and start of treatment for FREED and TAU groups. FREED participants waited significantly less time, on average, from referral to specialist assessment than TAU, with those who did not face gatekeeping barriers waiting just 2.6 weeks on average. Within the FREED cohort, wait time for assessment significantly differed by treatment site, with patients at SLaM (where stringent gate keeping arrangements were common) waiting significantly longer than patients from all other sites ($p<0.05$). This difference became non-significant when delayed patients were excluded from the analyses ($p= 0.115$). Kaplan-Meier survival curves were constructed to illustrate the cumulative probability of waiting to attend a clinical assessment according to days since referral. Figure 3 illustrates that the introduction of FREED was associated with a highly significant difference in the probability of being seen promptly, particularly when FREED was delivered under optimal conditions (log-rank test $x^2= 107.03$, df=2, $p <0.001$).

INSERT FIGURE 3 HERE

Treatment

On average, FREED participants waited significantly less time from referral to start of treatment than the TAU, particularly when gatekeeping was minimal. Within the FREED cohort, wait time from referral to start of treatment did not differ by diagnosis (p=0.341)

however there was a significant difference in wait time by site ($F(3,73)=12.521$, $p<0.001$), with wait time for treatment being substantially longer at SLaM than at all other participating sites. Once delayed patients were excluded, only a significant difference between SLaM and LYPFT remained, such that wait time for treatment at LYPFT is, on average, 3.07 weeks shorter than at SLaM ($p<0.001$; Hedge's $g = 0.78$). Kaplan-Meier survival curves were constructed to illustrate the cumulative probability of waiting to start treatment according to days since referral. Figure 4 illustrates that the introduction of FREED was associated with a significant increase in the probability of commencing treatment quickly after referral (log-rank test $x^2= 120.92$, df=2, $p <0.001$), and that this difference is even more pronounced when start of treatment for FREED participants was defined as the assessment.

INSERT FIGURE 4 HERE

Treatment Uptake

A greater proportion of individuals in the FREED group, compared to those in TAU, took up treatment after assessment (FREED:97.8%, TAU: 75.4%; X^2 (1, N = 502) = 59.79, $p<0.01$).

Discussion

This multi-centre study evaluated the impact of FREED, an early intervention service model and care pathway for adolescents and emerging adults with recent onset ED, on DUED and on service-related components of DUED. Overall, FREED patients had a significantly shorter DUED and faced shorter waiting times for both assessment and treatment than patients similar in age and illness duration seen previously in participating services. These differences were more pronounced when FREED was delivered under optimal circumstances, i.e., without external delays like complex gatekeeping or transitions between services. Further, the proportion of FREED patients taking up treatment was significantly higher than in TAU,

suggesting that a shorter interval between help-seeking from primary care and an offer of specialist assessment/treatment has clear down-stream benefits.

Our findings are encouraging compared to those of the German Psychenet study, the only other study of early intervention for ED to date, which was unsuccessful in its attempt to reduce DUED in patients with AN (Gumz et al., 2018). FREED-AN patients had an average DUED of approximately 14 to 17 months depending on whether FREED was delivered under optimal conditions or not. Whilst this is less than half the DUED of patients in the German study, it remains considerably longer than the DUEDs found in several recent studies of children and adolescents with AN, which range between 6 and 14 months (Andrés-Pepiñá et al., 2020; Bühren et al., 2013; Lieberman, Houser, Voyer, Grady, & Katzman, 2019; Nicholls, Lynn, & Viner, 2011; Weigel et al., 2014). This is unsurprising, as in younger children mealtime behaviour is much more closely monitored and supported by parents than in older adolescents and emerging adults. In our sample only 54% of patients still lived with their family.

The magnitude of the effect of FREED on DUED was noteworthy, particularly when FREED was delivered under optimal conditions (*Hedge's g= -0.38)* and specialist assessment is considered start of treatment (*Hedge's g= -0.47)*. Moreover, the effect sizes observed are comparable to those reported in early intervention studies for first episode psychosis. A recent meta-analysis found that stand-alone specialist early interventions, loosely comparable to FREED, reduced duration of untreated psychosis with a pooled effect size of *Hedge's g*= -0.38 (Oliver et al, 2018).

Although FREED was able to reduce service-related components of DUED, only 56% of patients received FREED as intended, and a sizeable portion of patients were affected by lengthy delays beyond our control. The most common reason for patients not receiving

FREED as planned were delays related to consecutive involvement of different services, for example transfers between services or transitions from child and adolescent to adult ED services. This speaks to the fact that these transitions can compromise the quality of care provided (McClelland et al., 2020). Another common reason for delay was the presence of systemic commissioning barriers, such as referral panels or individual commissioners making decisions about access, which prevented patients from receiving timely care. Many were affected by patient-driven delays, typically where university students were referred during term time but were then unavailable for assessment or treatment as they had returned home for university holidays. This reflects the transitory nature of this group of young people and highlights the need for services to be extremely flexible in engaging and treating them, e.g., through use of teleconferencing consultations and online or blended treatments (Giel et al., 2015; Sánchez-Ortiz et al., 2011). Greater flexibility in service transitions, reducing commissioning barriers and allowing self-referrals may also go some way towards reducing these delays.

Of note, a substantial proportion of patients who may have been suitable for FREED were not reached. Amongst the 995 patients excluded from FREED, there were 121 referrals who were within the FREED age range but could not be contacted after referral or did not attend their assessment (see Figure 1). This suggests that help-seeking in these young people is a delicate and potentially fragile process, and that they are often ambivalent about seeking and receiving support (Potterton, Austin, Allen, Laurence & Schmidt, 2020). While FREED goes a long way to improving uptake and engagement with specialist care amongst first episode cases, more needs to be done to bridge the gap between primary care and specialist services.

Lastly, whilst FREED was able to significantly reduce service-related components of DUED, the largest component of DUED was due to patient-related factors. With our onset interview we were able to retrospectively assess symptom development, progression and flux in the

FREED cohort: we found that on average young people were already at peak symptom severity for approximately 8 months prior to seeking help from their GP (Flynn et al., 2019). Two studies also investigated attitudes towards help-seeking and the characteristics of DUED in the FREED-Up cohort. A qualitative study found that early in illness, ED symptoms tend to be highly egosyntonic and help is not wanted. As symptoms become more compulsive and/or start to impact functioning, they are gradually reappraised. However, often stereotypical beliefs about EDs (e.g., EDs are characterised by extreme low weight; EDs are "teenage" illnesses) delay help-seeking further (Potterton et al., *submitted*). In a related study, FREED patients presenting to adult ED services (age 18 to 25) were directly compared to those presenting to Child and Adolescent ED services (below age 18). This study concluded that whilst symptom severity was similar in both groups, the younger patients had significantly shorter DUED (McClelland, 2019, *unpublished DClin thesis*). Together, these findings suggest that emerging adults presenting with a first episode ED are at risk of delayed help-seeking. This has important implications for future service development and research (Potterton, Richards, Allen & Schmidt, 2019).

The most noteworthy strength of the FREED-Up study is that it is a large-scale replication of our earlier single-centre pilot study of the implementation of FREED (Brown et al., 2018; McClelland et al., 2018). As in the pilot study, the implementation of FREED was associated with significantly shortened DUED, and reduced wait times for both assessment and treatment relative to TAU. In fact, where FREED was delivered under optimal conditions, mean wait times for assessment and treatment in FREED-Up were shorter than those reported in the pilot study (i.e., 2.6 weeks for assessment and 6.4 weeks for treatment in FREED-Up versus 3.7 weeks for assessment and 6.44 weeks for treatment in the FREED pilot). This finding speaks to the robustness of the FREED model and the rigor of our implementation. Similarly, in line with recommendations by Austin et al. (2020*),* a comprehensive, semi-

structured interview measure, anchored in key autobiographical events and dates, was used for the retrospective assessment of ED symptoms over time. A key limitation is the pragmatic quasi-experimental design: as participants were not randomised to receive either FREED or TAU we are limited in our ability to conclude a causal association between FREED and the reduction in DUED/wait times. Relatedly, ED onset was not estimated in the same way for both cohorts so it is possible that differences between the FREED and TAU cohorts may, at least in part, be explained by differences between the measurement tools. However, importantly, in both cohorts, service-related components of DUED were measured in exactly the same way (i.e., time from referral to assessment and start of treatment). This should increase confidence in the validity of the DUED measurement, and in the credibility of the significant large between group differences reported. Finally, as the TAU control population was identified retrospectively from clinical records, systematic differences between control patients and FREED-Up patients, which are unrelated to the intervention, are possible.

In conclusion, this study demonstrates that FREED is an innovative early intervention care package and service model which consistently and effectively reduces DUED and service-related components of DUED. Through our replication of pilot outcomes, we demonstrate that FREED may be successfully scaled to existing outpatient specialist ED services, with differing contexts, resources, and challenges. However, despite energetic efforts to shorten service-related components of DUED, the overall period of untreated ED remains lengthy, with the greatest period of unsupported ED occurring prior to referral by primary care. As such, further research into the earlier stages of DUED are needed. Similarly, greater efforts to bridge the gap between primary and specialist care are warranted.

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List of Figure Legends.

Figure 1. Participant flow.

Figure 2. Kaplan-Meier survival curve showing the cumulative probability of untreated ED according to time since illness onset.

Figure 3. Kaplan-Meier survival curve showing the cumulative probability of waiting for assessment according to days since referral.

Figure 4. Kaplan-Meier survival curve showing the cumulative probability of waiting to start treatment according to weeks since referral.

Table 1: Baseline Characteristics of FREED and TAU participants.

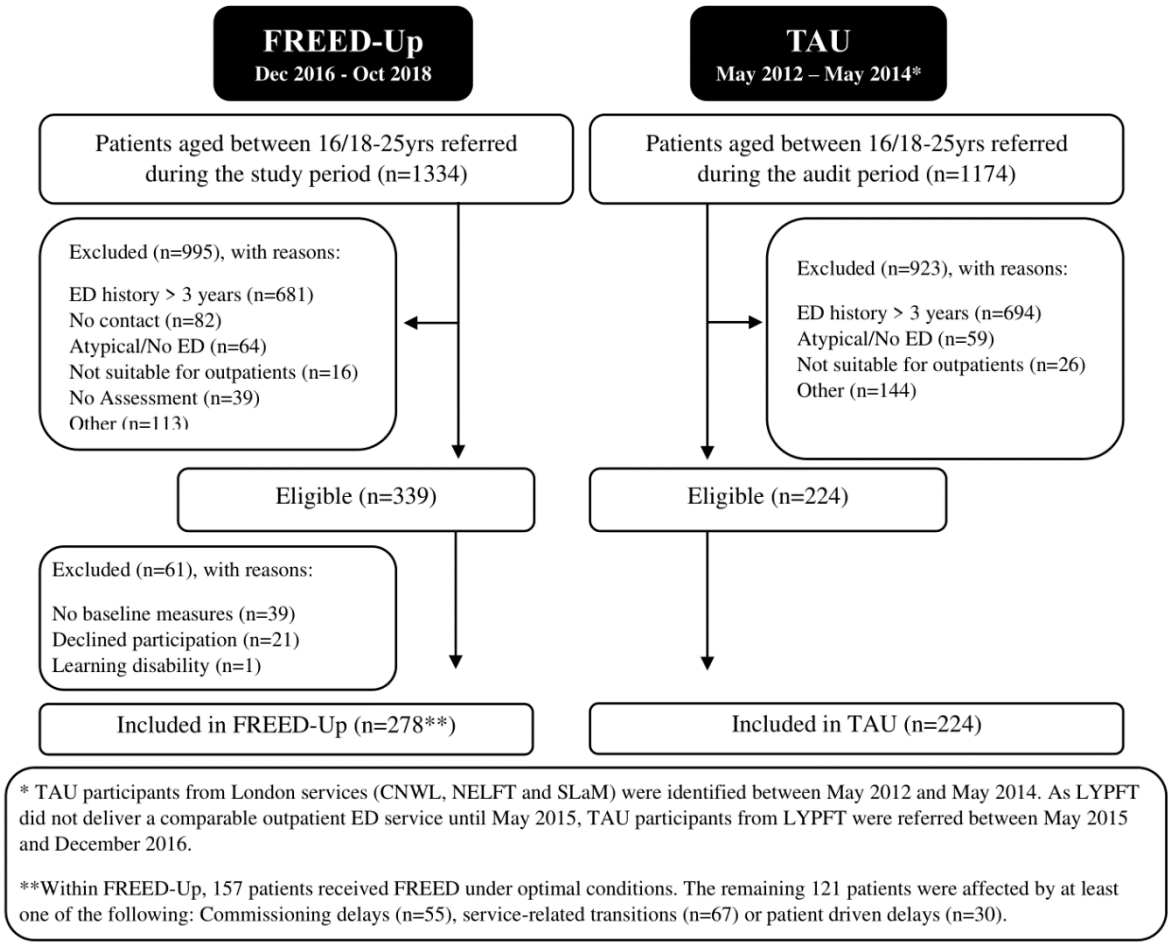
	FREED (*n*=278)	TAU (*n*=224)	t-test or z-test	Effect Size	95% CI
Age (M ± SD)	20.19 ± 2.39	20.28 ± 2.43	-0.41, $p = 0.68$	-0.03	-0.51, 0.33
Sex (F : M)	259:19	216:8	1.6, $p = 0.11$	1.98	0.85, 4.61
Diagnosis					
AN (n, %)	117 (42.1)	116 (51.8)	2.23, $p < 0.05$	0.68	0.48, 0.96
BN (n, %)	71 (25.9)	59 (26.3)	0.1, $p = 0.91$	0.98	0.66, 1.46
BED (n, %)	3 (1.1)	6 (2.7)	1.34, $p = 0.18$	0.40	0.10, 1.60
OSFED (n, %)	86 (30.9)	44 (19.6)	2.99, $p < 0.05$	1.89	1.24, 2.87
Ethnicity (n, %)					
White	181 (65.1)	174 (77.7)	3.08, $p < 0.05$	0.54	0.36, 0.80
Asian	27 (9.7)	21 (9.4)	0.14, $p = 0.99$	1.04	0.57, 1.89
Black	11 (4.0)	5 (2.2)	1.10, $p = 0.27$	1.80	0.62, 5.27
Mixed	20 (7.2)	7 (3.1)	2.01, $p < 0.05$	2.40	1.00, 5.79
Other/Unknown	39 (14.1)	17 (7.6)	2.29, $p < 0.05$	1.99	1.09, 3.63
Living Arrangement* (n, %)					
With Family	151 (54.3)				
Other	127 (45.7)				

Note: Z-tests compared proportions across the two groups and t-tests compared the means. Abbreviations: AN = anorexia nervosa, BN = bulimia nervosa, BED = binge eating disorder, OSFED = other specified eating disorder. ***** *Data on living arrangements were not available for TAU patients.*

Table 2: Differences between groups for mean duration from ED onset to specialist assessment (DUSC) and start of treatment (DUED) and mean waiting time from referral to specialist assessment and start of treatment.

Outcome	TAU (*n*=224, M ± SD)	FREED-Total (*n*=278, M ± SD)	FREED-Optimal (*n*=157, M ± SD)	Between Group Statistics									
				FREED Total v TAU					FREED Optimal v TAU				
				t	*df*	*p*	*95% CI*	*g*	*t*	*df*	*p*	*95% CI*	*g*
DUSC (months)	16.47 ± 10.41	16.82 ± 10.31	15.11 ± 9.58	.37	492	.71	-1.49, 2.13	0.03	-1.29	372	.200	-3.45, 0.72	-0.13
DUED (months)	19.98 ± 11.13	17.85 ± 10.38	15.95 ± 9.74	-2.0	424	<0.05	-4.23, -0.31	-0.20	-3.36	304	<0.001	-6.40, -1.68	-0.38
Assessment Wait (weeks)	6.72 ± 8.70	3.58 ± 3.79	2.56 ± 1.64	-5.41	500	<0.001	-4.28, -2.00	-0.49	-5.92	379	<0.001	-5.54, -2.78	-0.61
Treatment Wait (weeks)	20.76 ± 16.60	8.06 ± 5.73	6.36 ± 3.21	-11.53	429	<0.001	-14.86, -10.54	-1.15	-10.54	308	<0.001	-17.08, -11.70	-1.19
Treatment Uptake (*n*, %)	160 (71.43)	272 (97.84)	157 (100.00)										

Note: Where participants did not take up treatment DUED and wait time to treatment could not be assessed. As such, DUED and wait time for treatment were assessed for n=160 in TAU and n=272 in FREED-Total.



* TAU participants from London services (CNWL, NELFT and SLaM) were identified between May 2012 and May 2014. As LYPFT did not deliver a comparable outpatient ED service until May 2015, TAU participants from LYPFT were referred between May 2015 and December 2016.

**Within FREED-Up, 157 patients received FREED under optimal conditions. The remaining 121 patients were affected by at least one of the following: Commissioning delays (n=55), service-related transitions (n=67) or patient driven delays (n=30).

Figure 2. Kaplan-Meier survival curve showing the cumulative probability of untreated ED according to time since illness onset.

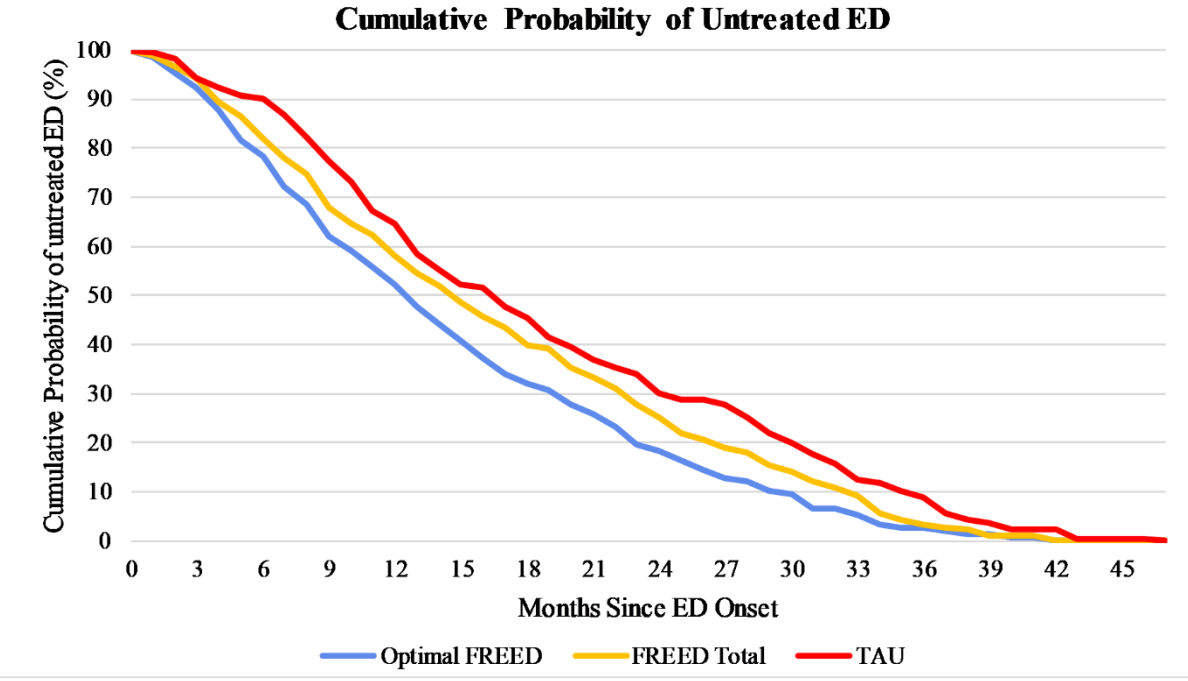


Figure 3. Kaplan-Meier survival curve showing the cumulative probability of waiting for assessment according to days since referral.

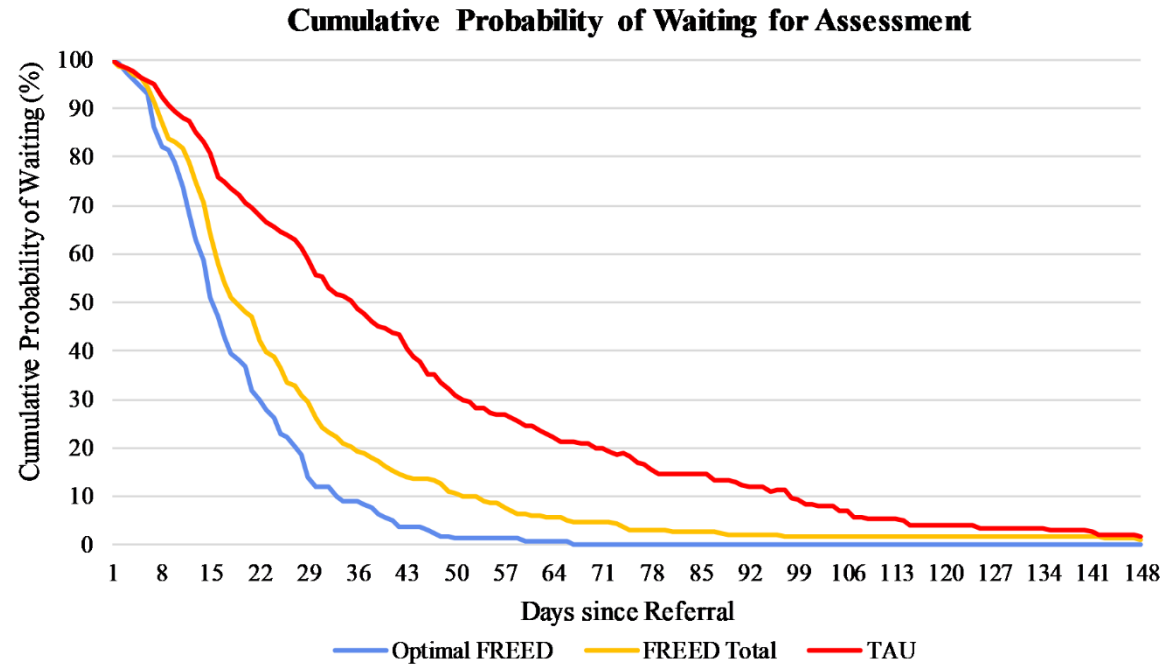
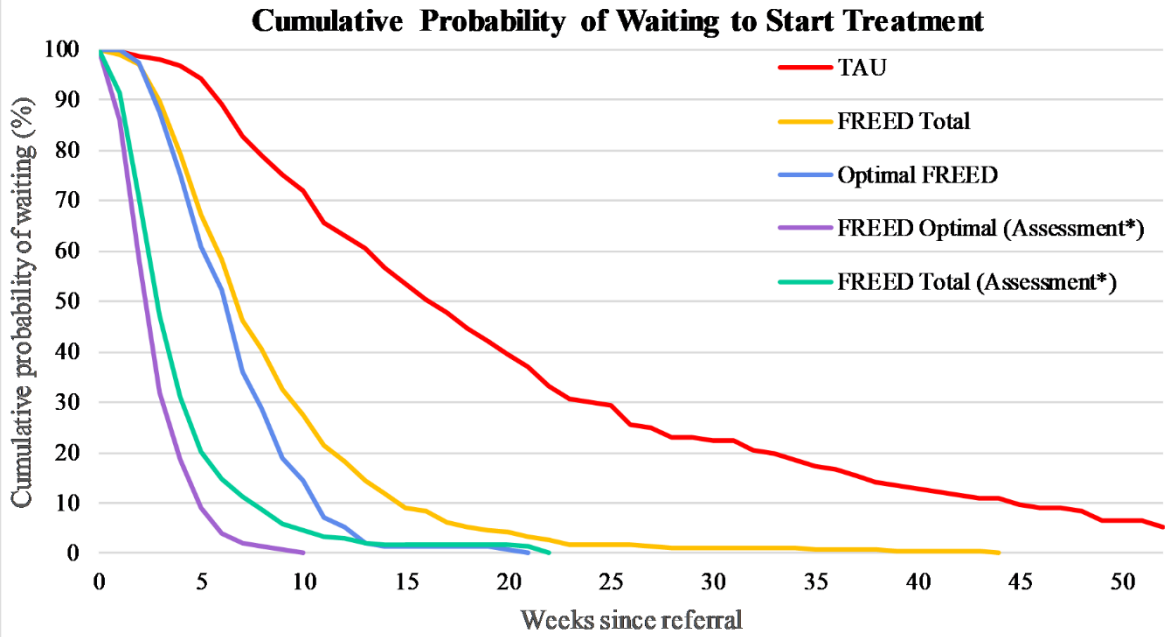


Figure 4. Kaplan-Meier survival curve showing the cumulative probability of waiting to start treatment according to weeks since referral.



Note: Assessment indicates that clinical assessment date constitutes start of treatment.*