A REVIEW OF THE CLINICAL EFFICACY OF AN INPATIENT EATING DISORDERS PROGRAMME

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A research report (in the format of a ''submissible'' paper) submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg in fulfilment for the requirements of the degree of Master of Medicine (Psychiatry), 2020.

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

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Signature of Student _____ Date: 6.10.2020

Name of primary supervisor: **Prof U Subramaney**

Signature of primary supervisor _____ Date: 7.10.2020

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Article title: **A review of the clinical efficacy of an in-patient eating disorders programme**

Authors:	Name	Signature	Date
1st author	Dr Jessica Clair Meddows-Taylor		7.10.2020
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Comments by primary supervisor:

This research paper is dedicated to the memory of my late father Dr Richard Morrison, and to my late supervisor Prof. Bernard Janse Van Rensburg.
There are no presentations **currently** having arisen from this research report.

ABSTRACT

Eating disorders remain the psychiatric disorders with some of the highest morbidity and mortality rates. Inpatient treatment of patients with eating disorders focusses on addressing both the medical complications of being underweight, as well as the psychopathology that drives the illness. This research study is a review of the demographic and clinical data of 57 patients admitted to the eating disorders unit at Tara hospital in Johannesburg over a 30-month period. Demographic as well as clinical data and the physical, psychosocial and psychological improvement was assessed over the period of admission. Associations between certain demographic and clinical features with psychological benefit were ascertained. The Eating Disorder Examination Questionnaire (EDE-Q), and Clinical Impairment Assessment (CIA) values reported on admission and discharge as well as changes between these values were utilised to demonstrate this. Findings of the demographic data were in keeping with the international findings of a predominant female, urban westernized cultured majority, with a split between adolescent (28%) and adult patients (72%). Overall, there was an improvement in the EDE-Q ($p<0.01$), the individual subgroups within the EDE-Q ($p<0.001$), and the CIA ($p<0.001$). Specific demographic factors which were associated with better responses were: youth, being single and shorter duration of eating disorder course with lack of co-morbid psychopathology. The programme utilised at the Tara Hospital Eating Disorder's Unit shows benefit with improvement of eating disorder psychopathology and subsequent psychosocial impairment. Younger patients noted a significant benefit in comparison to older individuals.

ACKNOWLEDGEMENTS

I am most grateful to Professor Subramaney for her direction, patience and support during the conclusion of this study. I must extend my thanks to Dr Megan Jones, for the suggestion of this research topic, assistance and important detailed focus especially from the early stages of this endeavour. I would like to commend the staff at Tara Hospital for their kindness in managing such complicated patients.

I am hoping that this research may assist in illustrating the amazing work the Eating Disorder unit does under the co-direction of Dr Megan Jones.

To my husband and three phenomenal daughters who have travelled this road with me. I am so blessed.

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ABBREVIATIONS/ACRONYMS

AN: anorexia nervosa

AN B/P: anorexia nervosa binge-purge subtype

AN R: anorexia restrictive subtype

BN: bulimia nervosa

OSFED: otherwise specified feeding and eating disorder

EDNOS: eating disorder not otherwise specified

BMI: body mass index

CBT-E: cognitive behavioural therapy for eating disorders

EDU: eating disorder unit

MDD: major depressive disorder

PDD: persistent depressive disorder

ETOH: alcohol

Benefit of Cognitive Behavioural Therapy for Eating Disorders (CBT-E) as a component of inpatient treatment – a review from a specialised South African Eating Disorder's Unit

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The authors declare that there is no conflict of interest.

ABSTRACT

Background: Eating disorders have a longstanding negative impact on patient health and quality of life. Inpatient treatment of patients with eating disorders focusses on addressing both the medical complications of being underweight, and the psychopathology that underlies the behaviour and ideation driving the disorder.

Setting: This article reported on a retrospective study of 57 women and adolescent females admitted to the Eating Disorders Unit (EDU) at the Tara Hospital, Johannesburg between July 2014 and December 2018.

Objective: To establish the demographic and clinical data of patients admitted to the EDU, and to review physical, psychosocial and psychological improvement following a period of inpatient care. The demographic features associated with better responses on self reporting will be described.

Method: Available demographic and anthropometric information on admission and on discharge was collected and reviewed. These were compared with values in the CIA[a] and EDE-Q[b] on admission and discharge. The CIA was utilised to review the quality of life in three specific domains whilst the EDE-Q quantified the impact of psychopathological thoughts and behaviours around weight, shape, food and compensatory behaviours that are employed.

Results: Overall, there was an improvement in the EDE-Q ($p<0.01$), the individual subgroups within the EDE-Q ($p<0.001$), and the CIA ($p<0.001$). This was particularly with certain pathological ideations that are core to the development and maintenance of eating disorders. There were specific demographic factors which were associated with better responses namely youth, being single and shorter duration of eating disorder course and lack of co-morbid psychopathology. Demographic data compiled was in keeping with the international findings of a predominant female, urban, westernised cultured majority, with a split between adolescent and adult patients.

Conclusions: The programme implemented at Tara's EDU shows benefit with improvement of eating disorder psychopathology and subsequent psychosocial impairment. Younger, single patients with no comorbid psychopathology and shorter eating disorder history fare better with an admission, with the only feature associated with greater improvement on the EDE-Q being that of younger age.

[a]: Clinical Impairment Assessment [b]: Eating Disorder Examination Questionnaire

Keywords: AN Anorexia Nervosa, AN B/P – anorexia nervosa binge purge subtype, AN R – anorexia restrictive subtype, BN – bulimia nervosa, OSFED – otherwise specified feeding and eating disorder, EDNOS – eating disorder not other specified.

Background

Eating disorders afflicting women in Western society today [1] remain common yet therapeutically challenging. These disorders have high relapse rates[1] and protracted courses[2] and if not aggressively treated, patients may suffer lifelong disability and even mortality.[3] DSM-5describes three larger groups of eating disorders, namely: bulimia nervosa (BN), anorexia nervosa (with binge-purge, and restrictive subtypes), and OSFED (otherwise specified feeding and eating disorder). Historically, eating disorders have been associated with multiple risk factors all contributing to varying degrees. [5,6,9] The development of eating disorders is associated with Western culture, where leanness and restraint over food intake are valued and encouraged. [5,10]

Psychiatric comorbidities

Eating disorders have a strong correlation with affective disorders, in particular depression, mood intolerance, and anxiety. [5,8,10] Salbach-Andrae [9] documented a 73% co-morbidity of major depression and anxiety. Solmi and colleagues [10], however, recognized that depressive symptoms, anxiety, and poor interpersonal relationships may be the effect of the eating disorder (both physiologically and socially). Personality features such as obsessiveness, perfectionism and low self-esteem are clearly co-morbidly associated psychopathology.[5,8,10,11] The most common personality types noted in anorexia nervosa (AN) are obsessive compulsive, avoidant, and dependent, whilst borderline personality disorder features are more commonly found in bulimic patients and those with the binge-eating/purging subtype of AN. [20]

Course of the Illness

De Galle [2] recognises that both AN and BN can have a chronic course (15% and 23% respectively). Poor prognostic factors for AN are older age of onset, bulimic symptoms, vomiting, somatic and psychiatric comorbidities (such as obsessive-compulsive personality disorder), [4,12,13] and lower body mass index (BMI) on admission to inpatient treatment.[14] Vall and Wade[13] showed that less severe concerns regarding weight and shape were associated with better outcomes. In BN, childhood obesity, certain personality elements and low self-esteem are described as poor prognostic factors.[12,13] OSFED incorporates presentations of both atypical or sub-diagnostic AN and BN, and share similar prognostic co-morbidities with the fully-fledged conditions.[15]

Epidemiology

South Africa has poor data on the incidence of eating disorders due to the scattered population and restricted resources. Worldwide, the ratio of female to male patients with eating disorders is between 10 to 20:1. [16] The onset of eating disorder pathology commonly occurs during adolescence due to hormonal shifts.[17] In Westernised countries, the eating disorder patient is stereotypically white, adolescent and female. However, there is an increasing incidence of eating disorders in minority groups, males and non-white patients.[18]

Inpatient vs outpatient

Eating disorders can be successfully managed on both an inpatient and outpatient basis. [19] According to the TOuCAN Study in the United Kingdom, with five year follow up of patients, inpatient programmes are not necessarily more clinically effective than outpatient programmes.[20]

The majority of patients with eating disorders are managed in an outpatient setting [4] as first line treatment, but certain individuals require inpatient management. Inpatient treatment is an expensive and labour-intensive alternative, but can be necessary when patients become medically unwell or do not respond adequately to outpatient interventions.[5] It is recognised as essential in severely underweight patients since the mortality of anorexia patients is twice that of any other of psychiatric condition.[2, 4, 21]

Inpatient care offers physical and nutritional rehabilitation and an opportunity for psychological intervention to address, inter alia, underlying problematic thinking and aversion to troubling or anxiety-provoking emotional states. [4,8] It can provide relief to the patient's family and reduce compensatory behaviours.[21]

Options for therapy

Fairburn and colleagues[22] propose that whilst the three main types of eating disorders (AN, BN, and atypical eating disorders) have distinctive clinical features, all are maintained and driven by similar psychopathology, and share many commonalities. This is known as the "transdiagnostic" view of eating disorders, and holds that AN, BN, and OSFED all share the following three criteria:

(1) over-valuation of shape, weight and eating control;

(2) persistent disturbance of eating habits / weight control behaviours; and

(3) impairment of physical health or psychosocial functioning.[7]

Patients frequently shift from one predominant presentation to another over time (diagnostic migration) [2,8] and, whilst at different times the behavioural and physical symptoms may differ, the core psychopathology typically stays the same.[4, 22]

Psychotherapy is typically a core component of all inpatient or outpatient treatment programmes. [5] Studies describe specific forms as being more efficacious in the different subtypes of eating disorders. Enhanced Cognitive Behaviour Therapy (CBT-E), an adapted form of CBT for eating disorders, is often considered the treatment of choice for adult outpatients with BN,[23] and has also shown good results for the treatment of AN, BN, and OSFED in adults and adolescents in a specialised inpatient setting.[14]

Predictors of response to intervention

Fichter and Quadflieg [24] who reviewed the six-year outcomes after inpatient programme completion, showed that low body weight on discharge predicted unfavourable outcomes. Better outcomes are associated with higher motivation, higher self-esteem, and the acknowledgement of hunger during admission.[12] Adolescents generally had a better outcome than adults, possibly due to earlier diagnosis, often within a year of emergence of symptoms.[25] An early age at onset, shorter duration of treatment, no relapses, higher socioeconomic levels, and higher level of education were all predictors of better outcomes.[25,26] In the TOuCAN Study, lower levels of self-reported eating psychopathology at baseline was also a notable predictor of a poorer long-term outcome.[20]

Eating Disorders (ED) in South Africa

Several studies on eating disorders have been conducted in South Africa, but the actual incidence of eating disorders in this country is not known. [6]

South Africa's rich cultural diversity lends itself to studies of eating disorders across the different demographic and racial groupings. Szabo and Hollands [17] described the increasing trend of eating disorder attitudes in the previously low-risk black adolescent population in Johannesburg due to increasing Western influence. Szabo and Morris [28] reviewed the impact of "Westernised" pressures around body image on adolescents in high schools within the Kwa-Zulu Natal province of South Africa. This adolescent group has mixed traditional and cultural rituals around social over-eating blended with Westernised ideals, making it a high risk group for the development of eating disorders.

Tara Hospital's Eating Disorder Unit (EDU) has been the site for four studies into eating disorders. Direct comparison of these studies is challenging as a result of poor record

keeping relating to changes in the various programmes. The current two-programme approach was implemented in 2003.

The demographics of ED patients admitted to Tara have been examined across different periods: Norris [5] (1976 – 1978; n = 54; 8 bedded unit), Szabo and Gabriel [18] (1987 – 1996; n = 254; anorexic unit), Vahed[29] (2001 – 2002; n = 59; anorexic patients), Abrie[30] (2005 – 2008; n = 42; anorexic patients). All studies reported that Tara inpatients were mainly Caucasian, single, younger than 40, and female, although Szabo and Gabriel[18] reported a trend for increasing age and decreasing socioeconomic class of admitted patients over time (comparing findings with earlier reviews of patient demographics).

A few studies have also looked specifically at the change in the race and gender of patients admitted to Tara's EDUs over time [5,6, 18, 29, 30,31]. Szabo and Gabriel [18] reported in their 10-year study (1987 – 1996) of admissions to Tara's EDU that only white patients (and very few males) were admitted in the study period. In contrast, between 1998 and 2004, Delport and Szabo [6] found an increase in non-white and male admissions.

Vahed's [29] study looked at the different characteristics in patients admitted for the different subtypes of AN, finding that 45% of admitted patients with AN had the restricting subtype whilst the remainder suffered from the binge-purge subtype.

Setting

Currently, and for the study period, the EDU at Tara Hospital has eight beds for AN, BN, or OSFED patients who are too unwell for outpatient treatment or for whom outpatient care has failed. The unit receives referrals from Southern Africa, and patients must be 13 years or older. Younger eating-disorder patients requiring inpatient care are admitted to the Children's Ward.

The aim of admission is to re-establish a healthy weight through weight restoration and/or to facilitate weight maintenance; to stabilise eating patterns; to limit or stop compensatory behaviours; and to address the core psychopathology of the ED (e.g. over-evaluation of shape and weight and marginalisation of other important life areas). Patients are treated by a multidisciplinary team, including nurses, psychiatry staff, an occupational therapist, dieticians, clinical psychologists, and a social worker. [9] The primary psychotherapy intervention since 2008 has been CBT-E.

The unit runs two similar programmes, each comprising six stages. The first programme focuses on weight restoration, and the second focuses on weight maintenance. Length of

stay varies, with discharge dependent on achievement of a minimum expected healthy weight range.

Depending on the patient's weight on admission and food intake prior to admission, the initial diet is between 800kcal and 1500kcal. The calories are subsequently adjusted to obtain a weight gain of between 750g and 1,5kg per week (weight restoration phase) or to allow for weight maintenance (weight maintenance phase).

Materials and methods

Study design

Our objective was to establish the demographic and clinical data of patients admitted to the EDU, and to review physical, psychosocial and psychological improvement following a period of inpatient care. A retrospective file review was conducted on all patients admitted to the EDU from July 2014 and discharged by the end of December 2018. Demographic data, anthropometric and clinical features were extracted. This data was then linked to results from questionnaires (CIA and EDE-Q) conducted on admission and discharge, and changes in the questionnaire values then analysed. The type of study design is thus a pre- and post-repeated measures programme evaluation.

Participant selection

Study participants included all patients admitted to the EDU during the study period. The unit treats adolescents and adults with eating disorders (ED) and co-morbid psychopathology. Most patients admitted suffered from anorexia nervosa (AN) with low weight and associated medical conditions. Initial eating disorder and co-morbid psychiatric diagnoses were made upon admission by a trained psychiatric registrar and consultant psychiatrist. The diagnoses were based on DSM-5 criteria.

Of the 65 patients admitted over this period, only 63 files were located. Six were excluded due to diagnoses not consistent with that of AN (anorexia nervosa), BN (bulimia nervosa) or OSFED (e.g. patients admitted for refeeding from a medical condition). A final study cohort of 57 patients was identified.

Study variables and outcomes

Demographic and clinical information collected from the patients' files included: date of birth (to calculate age on admission); gender; race; marital/relationship status; highest level of education; employment status prior to admission; weight at first and last Monday weigh-in, height, BMI, and percentage of minimum expected weight on admission and discharge; average rate of weight gain (kg/week) in weeks preceding reaching minimum expected

weight; calorie intake; length of admission (days); number of previous admissions to EDU facilities; completion of programme or RHT, previous or current co-morbid psychiatric or substance use conditions; duration of ED; age of onset of ED and type of ED on admission (AN-R; AN-BP; BN; OSFED). The factors 'mental health care status', 'languages spoken', 'home language' were eliminated from the study due to conflicting data within files.

Anthopometrics

Patients' weights and heights were recorded by trained staff at the time of admission and repeated on the first Monday after admission. Thereafter, weekly weights were obtained on Monday morning first thing in light clothes with shoes removed. Periodic height measurements of 'growing' adolescents necessitated recalculation of the BMI. The ward uses a standardised hospital grade fixed stadiometer with a digital scale. Weights were recorded to the closest tenth of a kilogram. Heights were recorded to the nearest tenth of a centimetre. BMI was calculated using the standard formula (kg/m^2). Minimum expected weight was calculated using a BMI of 20. The minimum expected weight for adolescents (17 years and younger) is calculated based on the 50^{th} percentile BMI for a similarly aged child (as per CDC growth charts). Occasionally, for patients who are not of reproductive age and who have had a chronic course of the disorder, the team aimed for a slightly lower BMI of between $18.5kgm^{-2}$ and $19kgm^{-2}$.

Psychometric measures

The scores and subscale scores for The *Clinical Impairment Assessment (CIA) Questionnaire* and *Eating Disorder Examination Questionnaire (EDE-Q)* administered at the start and end of each programme were recorded.

Worldwide, programmes that used CBT-E (Cognitive Behaviour Therapy for Eating Disorders) typically use the EDE-Q and CIA to measure improvements as a result of treatment. [26] These rating scales have been used in the programme since June 2014.

The EDE-Q has been widely used in international studies. [32] The EDE-Q documents the psychopathology behind the development of an eating disorder and in doing so highlights the driving force(s) behind the maladaptive behaviours. It is a 'self-report' questionnaire. The EDE-Q comprises 28 items focussing on symptom occurrence in the preceding 28 days, and reviews the four different domains core to ED psychopathology: restraint (5 items), eating concern (5 items), shape concern (5 items) and weight concern (8 items), It provides one global score ([sum of subscale scores]/4). Scores of four or higher are considered to be

within the clinical range,[10] with higher scores indicating higher psychopathology severity or frequency.[35] There are an additional six items (not included within global or subscale score calculations) which assess the frequency of bingeing and compensatory behaviours. The EDE-Q has good psychometric properties and is often used to measure response to treatment. [7] It has acceptable levels of internal consistency for its global and subscale scores, good concurrent validity with the EDE[32] and satisfactory test-retest reliability.[33]

The Clinical Impairment Assessment (CIA) [15]

The CIA is a disorder specific review of the impairment experienced as a result of the eating disorder. [33] It was developed to assess the impact that eating disorders might have on all areas of psychosocial functioning. This is an illness-specific, self-reporting, questionnaire which follows the Likert 4-point format like the EDE-Q, reviewing the impact the main areas of psychopathology in eating disorders have on impairment. [25] It relates to the previous 28 days, and is designed for co-administration with the EDE-Q. It is a brief questionnaire with 16 different items covering four specific domains of life where impairment can be identified: mood and self-perception; cognitive functioning, interpersonal functioning, work performance. Each item is scored (from 0, not at all, to 3, a lot).

A single global score is calculated which ranges between 0 and 48, such that the higher the score, the greater the impairment. A global score above 16, indicates significant impairment. [34]

Reviews indicate the CIA shows good test-retest reliability, construct validity, and sensitivity to change, and hence is used widely in research models worldwide. [15]

Both measures are scales that were administered in English or, where necessary, Afrikaans. Neither has been validated in the South African context.

Patient files in which either the pre-admission or discharge questionnaire was absent or were more than 20% incomplete were excluded from the analysis. Questionnaires with unanswered questions were re-analysed to calculate for only those complete subscales.

Statistical analysis

The data which describe the sample, that is, the demographic and clinical characteristics of the study sample, were initially generated and captured. This was done in groups for continuous variables (for example, age) and frequencies and percent distributions for categorical data (for example, racial grouping). In addition, reliability information regarding the data collection instruments was generated.

Statistical hypothesis testing was performed to gauge the statistical significance of improvement, or lack thereof, in EDE-Q and CIA scores from admission to discharge. Pearson's correlation and, in cases, linear regression with ANOVA on the fit model and its parameters, were used to determine the association between variables. For example, clinical variables such as demographic factors (e.g. age, etc) were studied making use of Pearson's correlation relative to the EDE-Q and CIA scores as well as linear regression of the variables in question against the EDE-Q and CIA scores. The statistical significance of the Pearson's correlation and the linear regression, its parameters and the associated ANOVAs were determined at the level of $p<0.05$ In support of multivariate analysis, the parametric Paired Samples *t*-test was used to compare the indices of the study sample with respect to the admission and discharge variables of interest for EDE-Q and CIA measurements. In order to ascertain those factors which predict better outcomes from admission, a multivariate binary logistic regression analysis was performed. Improvements in the parameters/scores/indices regarding physical health, behavioural and psychological measures of eating disorder psychopathology (EDE-Q) and psychosocial impairment secondary to the eating disorder (CIA) were identified. The statistical significance of these variables was also tested.

Results

A total of 57 files were reviewed for the 30-month period. All patients were female, with 47 (82.46%) being Caucasian (Figure 1). Of all the patients, 39 (68.41%) were diagnosed with anorexia nervosa with only a slight majority being those with the binge-purge subtype (35.08% v. 33.33%) (Figure 3). The majority of patients were either older than 35 years (n= 17, 29.82%) or younger than 18 years (n= 16, 28.07%) at the point of admission (figure 2), with a higher number of patients having completed the ED programme being duly discharged (n= 39, 68.42%) (table 1). However, close to a quarter of those admitted to the programme left with refusal of hospital treatment (RHT). A combined percentage of 75.44% of these had been admitted previously for eating disorder pathology with 21.05% having been admitted more than twice before (table 1). Those admitted were either newly diagnosed with eating disorder pathology i.e. less than 2 years (n= 27, 47.37%) or had suffered with an eating disorder for more than 10 years (n= 22, 38.59%) (table 1).

When patients were admitted, 78.95% (n= 53) were underweight (BMI <20 kg/m^2), and the greatest proportion (19.30%, n=11), had a BMI of 15.01-16.50 kg/m^2 (table 1). The average length of admission in the unit was 114 days. There was a history of one of more family members with an eating disorder history (restrictive, binge eating or obesity) in 32% (n=17) of the patients, with 56% (n= 33) of patients having one or more family members with a history of other psychiatric illness (table 1). The most common co-morbid substance disorder in the patient group was that of alcohol (ETOH) abuse in 26.32% (n=15) of patients (table 1). The most common co-morbid psychiatric condition was anxiety in 50.88% (n= 29), with borderline personality disorder in 36.84% (n= 21) of the patients (Figure 4).

When reviewing changes in questionnaires over admission, there were only 37 complete CIA and 52 EDE-Q questionnaires to compare. Analysis showed a clear improvement in the clinical impairment (CIA) experienced by patients after admission ($p< 0.01$), with greater improvement seen in the total psychopathology (EDE-Q) described by patients ($p<0.001$) (table 2). Of note there were however 28.8% (n= 10) of patients who noted a decline in scores.

Additional review of specific improvements in the subgroups showed improvement in all, especially in *eating concern* and *restraint*. Only *excessive exercise* showed a statistical improvement through admission ($p<0.001$) (table 2).

Table 1: Socio-demographics and clinical review of study group

Gender	**N – total 57**	**%**
Female	57	100
Racial group		
African	3	5.26
Caucasian	47	82.46
Indian	2	3.51
Mixed race	5	8.77
Age		
13-18	16	28.07
19-25	11	19.3
26-35	13	22.81
>35	17	29.82
Diagnosis		
Anorexia nervosa (restricting subtype)	19	33.33
Anorexia nervosa (binge purge subtype)	20	35.09
Bulimia nervosa	10	17.54
OSFED (any subtype)	8	14.04
Completion of ED programme		
Refused hospital treatment	14	24.56
Completion of programme	39	68.42
Other	4	7.01

No. of previous eating disorder admissions		
Nil	14	24.56
1	18	31.58
2	13	22.81
>2	12	21.05
Number of admissions over study period		
1	39	68.42
2	6	21.05 of admissions
3	2	10.53 of admissions
Number of years of eating disorder prior to admission		
<- 2	27	47.37
3-10	8	14.04
>10	22	38.60
Body mass index (BMI) on admission (kg/m2)		
<11.0	2	3.51
11.01-13.50	9	15.79
13.51-15.00	7	12.28
15.01-16.50	11	19.30
16.51-18.00	7	12.28
18.01-18.50	3	5.26
18.51-20.00	6	10.53
20.00 >, <25.00	8	14.04
>25.01	4	7.02
Length of admission (days)		
<30	7	12.28
31-60	5	8.77
61-90	9	15.79
91-120	8	14.04
121-150	13	22.81
151-180	7	12.28
>180	8	14.04
Average length of admission (days)	114	
Maximum calories reached		
1500	11	19.30
1750	9	15.79
2000	8	14.04
2250	16	27.07
2495/2500	8	14.04
2750/2800	4	7.02
3000	1	1.75
Highest level of education		
Currently in high school (grade 7-11)	23	40.35
Matric	12	21.05
Batchelor's degree	6	10.53
Diploma	6	10.53
Honour's degree	1	1.75
0-level	1	1.75
Currently enrolled in tertiary education	6	10.53
Family history of eating disorder – no. of family members		
Nil	39	68.42
1	13	22.81
2	3	5.26
>2	2	3.51
No. with a family history of psychiatric disorders		
Nil	24	42.11

1	20	35.09
2	8	14.04
3	4	7.02
>3	1	1.75
No. with family members with major depressive disorder(MDD) or persistent depressive disorder(PDD)		
Nil	46	
1	19	33.33
2	2	3.51
No with family members with other mood or anxiety disorders		
Nil	50	87.72
1	7	12.28
No. with family suffering with alcohol use disorder		
Nil	33	57.89
1	19	33.33
2	4	7.02
3 or more	1	1.75
No. with family suffering with cannabis use disorder		
Nil	55	96.49
+	2	3.51
Patients with substance use – caffeine		
Nil	55	96.49
+	2	3.51
Patients with substance use – alcohol		
Nil	42	73.68
+	15	26.32
Patient with substance use – cannabis		
Nil	50	87.72
+		
Patient with substance use – nicotine		
Nil	50	87.72
+	7	12.28
Patient with substance use – laxatives		
Nil	48	84.21
+	9	15.79
Patient with substance use – stimulants		
Nil	53	92.98
1 form	3	5.26
2 forms	1	1.75
Patient with substance use – opiates		
Nil	54	94.74
+	3	5.26
Patients with co-morbidity of:		
Persistent Depressive Disorder (PDD)	25	43.86
Major Depressive Disorder (MDD)	10	17.54
Anxiety disorders	29	50.88
Patient co-morbidity personality disorder		
Nil	28	49.12
1 form	27	47.37
2 forms	2	3.51
Specific personality disorders		
Dependent	1	1.75
Borderline	21	36.84
Narcissistic	2	3.51

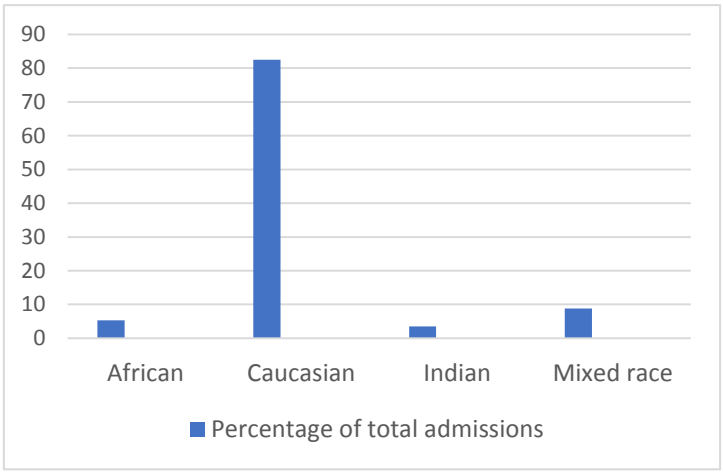

Figure 1: Racial distribution of patients admitted

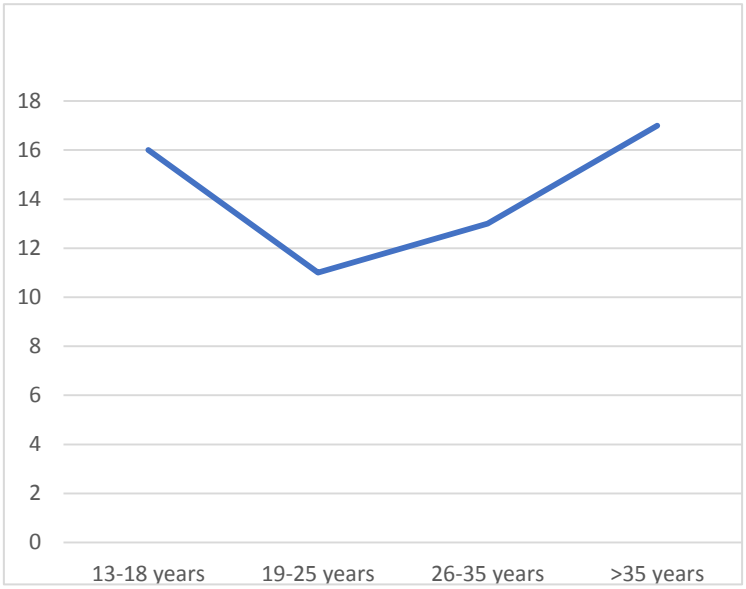

Figure 2: Age distribution of patients admitted

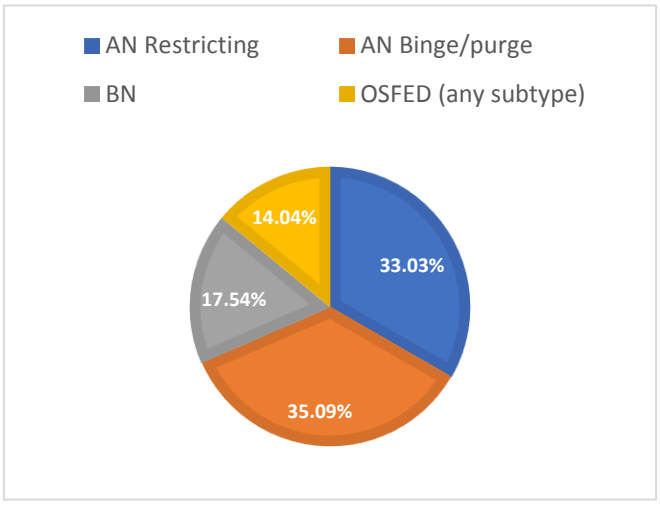

Figure 3: Percentage of different eating disorder subtypes

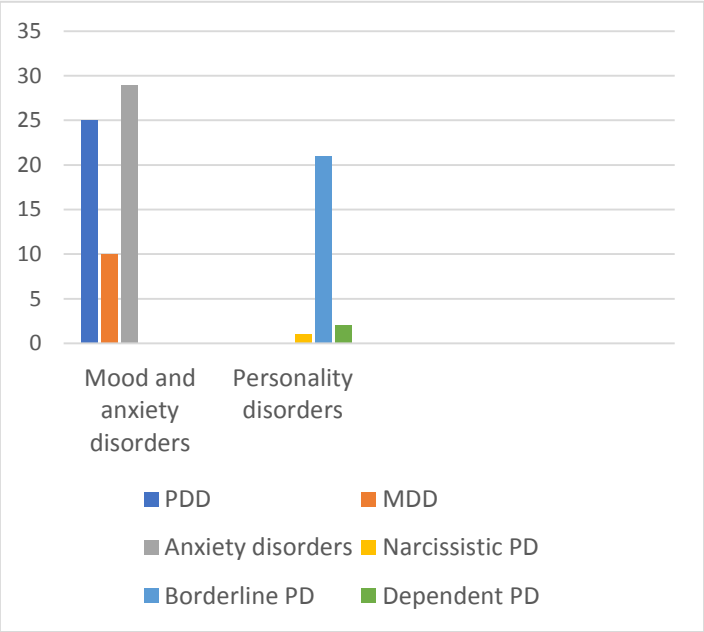

Figure 4: Numbers of patients with co-morbid mood, anxiety or personality disorders

Table 2: Improvements in scores on questionnaires from admission to discharge

	n	t-statistic	p-statistic	CI for improvement (95%)	Mean improvement	% Who improved	% Who deteriorated
CIA	37	5.74	1.54×10^{-6}	11.43 – 23.92	17.68	86.5	13.5
Total – EDE-Q	52	8.16	8.06×10^{-11}	1.62-2.68	2.15	71.2	28.8
Restraint subgroup	39	7.11	$\mathbf{1.77 \times 10^{-8}}$	1.66-2.99	2.33	79.5	20.5
Eating concern subgroup	39	6.77	$\mathbf{5.01 \times 10^{-8}}$	1.25-2.32	1.79	87.2	12.8
Shape concern subgroup	39	4.05	2.33×10^{-4}	0.69-2.07	1.38	79.5	20.5
Weight concern subgroup	39	4.16	1.78×10^{-4}	0.71-2.06	1.38	79.5	20.5
Behavioural changes							
Laxative use	39	2.06	4.59×10^{-2}	0.04-3.96	2.0	17.9	82.1
Excessive exercise	39	3.62	8.48×10^{-4}	7.48-8.75	5.62	43.6	54.5
Bingeing	39	1.70	9.74×10^{-2}	-0.80-9.21	4.21	46.2	53.8
Vomiting	39	0.18	8.62×10^{-1}	-4.33-5.15	0.41	25.6	74.4

Significant *p value* <0.01

Correlations:

Changes in both the total EDE-Q and the individual subgroups were correlated with each of the demographic factors, admission details and anthropometric data (table 3). It must be

mentioned that whilst some analyses showed a great percentage change, due to the small sample size this could be non-significant.

There was significant improvement in scores in younger patients (p <0.05), with the greatest found in the subgroup of *shape concern (p =* 0.007*)*, and the least in *restraint* (*p=0.467)* (table 3*)*. Within the racial groupings and ED diagnoses, there failed to be any clear statistical improvement within the groups themselves (table 3). In AN (binge-purge) patients, there was benefit seen in the area of *restraint (p =* 0.03*)* (table 3).

Demographic features such as *relationship status*, and *highest level of education* failed to show any overall improvement. Similarly, little benefit could be seen in specific clinical categories, family history of eating disorders (p=0.252) or psychiatric illness (p=0.665), co-morbid substance use or mood (p=0.175) / anxiety conditions (p=0.725). A co-morbid borderline personality was associated with improvement in overall scoring (p=0.04) (table 3).

Table 3: Correlation between demographic features, clinical features and improvement in total EDE-Q and subgroup scores (p-values represented in %)

	Total (%)	**Restraint (%)**	**Eating concern (%)**	**Weight Concern (%)**	**Shape concern (%)**	**Laxative use (%)**	**Excessive exercise (%)**	**Bingeing (%)**	**Vomiting (%)**
Age	-29.4	-9.9	-20.2	-31.8	-35.1	12.6	-5.5	-13.4	-17.0
***p* value**	**3.4‡**	46.7	13.1	**1.6‡**	**0.7†**	35.5	68.6	32.5	21.5
Racial grouping									
Caucasian	4.8	3.5	8.5	2.4	0.5	-9.7	10.7	-4.6	-11.1
***p* value**	73.4	79.3	53.2	85.7	97.1	47.8	43.5	73.7	41.6
Indian	14.6	11.5	15.2	10.9	11.5	-7.7	-11.8	13.3	13.3
***p* value**	30.0	40.0	25.9	42.2	39.2	57	38.5	33.0	33.0
African	-7.4	-2.2	-16.0	-18.4	-13.7	15.7	2.0	-6.8	-5.4
***p* value**	60.2	87.4	23.5	17.1	31.0	24.9	88.2	62.0	69.3
Mixed Race	-11.8	-11.4	-8.6	4.2	2.6	5.7	-8.2	2.9	10.5
***p* value**	40.7	40.2	52.4	75.8	84.6	67.8	54.8	83.3	44.0
Relationship status									
Single	4.4	1.9	-9.4	-4.7	2.3	-20.5	-9.2	18.8	-1.4
***p* value**	75.7	88.8	48.7	72.9	86.3	13.0	50.2	16.4	92.0
Married	-5.6	-5.6	-6.3	-0.7	-5.7	-8.4	-8.9	-23.1	-2.7
***p* value**	69.2	68.4	64.0	95.6	67.2	53.8	51.4	8.6	84.6
Divorced – not in relationship	3.2	8.7	-1.3	5.7	-2.2	30.2	15.5	-19.7	-1.3

***p* value**	82.2	52.3	92.5	67.4	87	**2.4 ‡**	25.2	14.7	92.4
In a relationship	-4.3	-5.3	19.5	2.5	3.3	10.6	7.6	10.7	5.6
***p* value**	76.4	69.6	14.6	85.5	80.6	43.5	57.9	43.1	68.1
Highest level of education									
Currently in high school	15.4	-2.4	10.8	14.6	12.5	-32.3	-5.7	6.7	13.3
***p* value**	27.6	86.2	42.3	27.7	35.5	**1.5‡**	67.4	62.5	33.0
Matric	-19.6	-10.6	-23.8	-28.2	-18.0	18.2	3.6	-13.2	-30.0
***p* value**	16.3	43.9	7.4	**3.4‡**	18.0	17.8	79.4	33.1	**2.4‡**
In university	-15.8	-22.6	0.0	-2.2	-3.6	0.5	-2.8	16.7	10.9
***p* value**	26.4	9.3	99.8	87.3	78.8	96.9	83.6	21.9	42.5
Diploma	15.7	29.1	10.4	19.5	16.6	38.3	24.8	3.8	3.1
***p* value**	26.6	**3.0‡**	44.2	14.5	22.0	**0.3‡**	6.5	78.0	82.1
Batchelor's degree	-0.9	7.1	1.4	-7.3	-11.8	-13.0	18.9	-15.7	2.3
***p* value**	95.0	60.3	91.6	59.1	38.1	30.5	16.4	24.9	8.4
Diagnoses									
Anorexia nervosa – restricting	17.3	22.2	1.4	16.0	15.8	-13.3	14.5	-19.5	-15.0
***p* value**	21.9	10.0	91.5	23.4	24.0	32.7	28.5	15.1	26.9
Anorexia nervosa – binge purge	--25.5	-28.5	1.3	-24.0	-21.3	21.7	-8.3	-6.7	-15.5
***p* value**	6.8	**3.1‡**	92.6	7.2	11.2	10.9	54.5	62.5	25.4
Bulimia nervosa	6.4	9.2	5.6	5.4	0.5	-3.3	-9.5	22.4	19.3
***p* value**	65.1	50.0	67.7	68.9	97.1	80.8	48.7	9.6	15.3
OSFED – BN spec	0.8	3.5	1.1	1.8	-2.8	-7.8	-11.2	-0.2	18.1
***p* value**	95.2	80.0	93.7	89.3	83.4	59.1	41.1	98.6	18.1
No. of previous ED admissions	-10.5	-10.6	-11.6	-9.5	-13.1	13.6	3.6	-27.1	-32.2
***p* value**	46.0	43.8	37.9	48.4	33.0	31.6	79.4	**4.3‡**	**1.6‡**
Number of years with an ED prior to admission	-22.1	-14.4	-25.0	-25.2	-23.8	3.1	-1.1	-21.9	-36.2
***p* value**	11.5	28.9	6.1	***5.9***	7.5	81.9	93.5	10.5	**0.6†**
BMI on admission	4.5	15.5	5.1	6.5	6.2	11.8	-8.0	24.6	27.5
***p* value**	75.0	25.4	70.7	62.9	64.8	38.4	56.0	6.8	**4.0‡**
Length of admission	-2.7	-4.0	-8.2	-6.6	-5.6	-0.6	-2.6	-17.5	-14.0
***p* value**	84.7	76.8	54.6	62.3	68.0	96.8	83.3	19.7	30.4
Maximum calories achieved	-17.2	-13.5	-7.7	-7.9	-13.5	-10.2	-16.2	-34.4	-27.5

***p* value**	22.3	32.1	56.9	55.8	31.7	45.3	23.7	**0.9†**	**4.0‡**
Family history of eating disorder	16.2	1.3	8.0	4.6	8.1	-10.1	-11.6	22.8	4.4
***p* value**	25.2	92.7	55.4	73.6	55.1	45.7	39.4	9.0	74.7
Family history of psychiatric illness	6.1	-13.2	-17.5	-2.0	-1.1	-20.1	-15.9	2.4	0.9
***p* value**	66.5	33.1	19.4	88.1	93.7	13.7	24.2	86.0	95.0
Family history of MDD/PDD	2.2	-6.2	1.8	-1.1	3.3	-6.1	-7.1	-3.5	-6.4
***p* value**	66.5	19.4	88.1	73.8	77.2	64.3	59.1	74.3	64.7
Family history of anxiety disorder	-0.5	-0.8	-8.5	7.0	-0.3	-9.5	-16.9	10.9	23.9
***p* value**	97.2	95.6	53.0	60.5	98.3	48.7	21.4	42.2	7.5
Patient co-morbidities									
Patient with comorbid MDD/PDD	-11.4	-12.2	-9.5	-8.2	-11.8	-10.4	-13.5	-12.2	6.9
***p* value**	17.5	28.4	37.5	51.6	37.6	44.9	32.0	43.5	33.4
Patient with comorbid anxiety disorder	-5.0	-20.8	6.1	-7.1	-1.0	-16.3	-11.8	12.0	3.1
***p* value**	72.5	12.3	65.1	59.8	94.0	22.9	38.7	38.0	81.9
Patient with comorbid ETOH use	9.6	-2.3	1.9	13.1	81	29.1	5.8	11.9	14.0
***p* value**	50.0	86.5	89.1	33.0	54.7	**2.9‡**	67.0	38.8	30.3
Patient with comorbid cannabis use	-3.7	-16.9	-10.7	-2.2	-3.3	4.8	-16.9	-3.3	11.9
***p* value**	79.8	21.2	42.6	87.3	80.6	72.4	21.4	80.9	38.1
Patient with comorbid nicotine use	-2.5	0.8	7.3	4.7	8.5	7.5	-5.3	-2.3	-8.2
***p* value**	86.0	95.6	59.0	73.0	52.8	58.3	69.8	86.9	54.6
Patient with comorbid caffeine use	2.7	25.9	5.1	12.5	13.0	44.6	23.4	-5.5	-3.1
***p* value**	85.2	5.4	70.4	35.5	33.3	**0.1†**	8.3	68.5	82.3

Patient with comorbid opiate use	-0.8	-5.1	-7.7	6.4	2.5	19.9	2.0	-7.3	1.9
***p* value**	95.7	70.6	56.8	63.7	85.3	14.2	88.2	59.4	89.1
Patient with comorbid stimulant use	18.9	-0.6	22.8	22.0	18.2	28.3	7.2	22.4	22.4
***p* value**	17.9	96.5	8.8	10.0	17.5	**3.5‡**	59.9	9.7	9.6
Patient with comorbid personality disorder	5.1	7.0	2.8	3.4	-2.7	29.3	-1.8	29.3	36.0
***p* value**	71.8	60.8	83.9	80.4	84.3	**2.8‡**	89.2	**2.9**	**0.6†**
Patient with borderline personality disorder	28.6	17.5	3.8	19.8	22.6	18.2	8.4	21.3	35.3
***p* value**	**4.0‡**	19.7	78.2	14.1	9.1	17.9	53.6	11.6	**0.8†**
Patient with narcissistic personality disorder	0.0	1.7	6.2	21.5	7.2	20.3	1.1	11.4	10.1
***p* value**	99.9	90.0	64.9	10.8	59.3	13.3	93.6	40.1	45.8

‡ - significant (p<0.05)/ <5%
† - highly significant (p<0.01)/< 1%

Discussion

In keeping with both international and local studies our patients were all female, and majority were Caucasian.[5, 9, 21] In Westernised countries, the eating disorder patient is stereotypically white, adolescent, and female.[33] Szabo and Gabriel[18] noted a similar predominance. Abrie [30] noted a different age group of patients, with all in her study being under 40. Our patient group consisted of adolescent or adult females. This may be attributed to both concern for initial symptoms in adolescents and requirement of admission, or readmission, for older patients with persistent symptoms and associated medical comorbidities. [21] We found only a slightly higher percentage of patients admitted with AN binge-purge subtype in comparison to the restrictive subtype. This is similar to other studies e.g. Vahed [29] but in contrast to Abrie [30] where admissions were more of the restrictive subtype. Restrictive subtypes of AN are a more common finding seeing the reason for inpatient management may be as a result of significant loss of weight and medical sequelae.

Variation in admission diagnoses may be attributed to the dynamic nature of eating disorders, often changing from one form to another over time. [14,15]

To our knowledge this is the first study reviewing the effects of the CBT-E programme on patients in the EDU at Tara Hospital in Johannesburg. There is only one study in the unit which has reviewed the efficacy of the programme itself. Szabo and Terreblanche [22] conducted a study reviewing the efficacy of the Tara inpatient unit between November 1993 and October 1995. It was concluded that the individual and family therapy was beneficial as an intervention. In the current study, data analysis showed similar significant improvement in both the psychopathology that drives and maintains eating disorders, and the psychosocial impairment that follows. This was demonstrated in the overall scores in the EDE-Q and CIA (table 2). Psycho-social rehabilitation in this study (demonstrated in the CIA) looks at cognitive, work performance and interpersonal engagement. There is a clear correlation between a higher BMI (as would be expected at discharge) and improvement in all these areas. [13]

The subgroups of the EDE-Q where greatest improvement could be seen was that of *eating concern* and *restraint* ($p<0.00001$) (table 2). These are core components of the CBT-E directive therapy and independently speak of efficacy. [2,14] With correlative analyses, it became clear that certain demographic features were associated with better outcomes on the EDE-Q and CIA. Younger patients fared better, possibly due to the less ''engrained psychopathology''. [13] Whilst there were suggestions that certain demographical or clinical groups may show statistical benefit, there was nothing statistically relevant. We expected longer pre-admission illness and lower BMI on admission to be associated with worse prognosis, and cognitive resistance. [12,14] There was no significant relationship between family psychiatric, substance use or eating disorder history and patient improvement. However, patients with co-morbid borderline personality traits fared better. This may suggest that the structured environment and removal from home circumstances could have proved beneficial.[12].

It is again important to note, that this was a limited sample size with much of the data excluded due to being incomplete, hence many correlations are not statistically significant. Limitations included the fact that the patients completed the final questionnaires in anticipation of their discharge. Hence this data may not have been consistently reliable. Neither questionnaire was validated in the South African context. It would be interesting to

investigate the association between the improvement in BMI and psychological benefits, however we were unable to do so in this study due to confounding variables.

Conclusion

This study showed that based on measureable outcomes, the EDU programme utilised currently at Tara Hospital provides successful treatment for a majority of eating disordered behaviour and the underlying psychopathology. It must also be noted that the direct effect of CBT-E alone could not be quantified. The patients that appeared to respond most successfully, with changes in the underlying psychopathology of eating disorders – were those of a younger age, suggesting that the less 'engraved' the pathological thinking, the more responsive they are to the effects of the programme.

Of concern is that almost a third of patients demonstrated a decline in scores over the period of admission. In light of the financial and personnel cost of the unit, further research to review demographic factors associated with better response rates, as well as research into 'post discharge' benefits may be beneficial.

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Ethics permission given by University of Witwatersrand Biomedical Ethics Committee, and the Tara Hospital Ethics Committee.

Author Details

Prof Ugasvaree Subramaney is the Head of the Department of Psychiatry at the University of the Witwatersrand and assisted with the supervision of the Master's degree upon which this article was based. She has multiple previous publications especially in areas around Post Traumatic Stress Disorder and female forensic mental health.

Dr Jessica Meddows-Taylor is a final year registrar in the Department of Psychiatry at the University of Witwatersrand. This article was submitted as her Masters of Medicine Research.

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Appendix A: Approval of Protocol

<table>
<tr><td colspan="2">CANDIDATE'S
SURNAME: Meddows-Taylor</td><td colspan="2">FIRST NAME/S: Jess</td><td>STUDENT NUMBER:
9803567D</td></tr>
<tr><td colspan="5">CURRENT
QUALIFICATIONS: MBBcH (Wits), Dip For Path (CMSA)</td></tr>
<tr><td>TEL:</td><td>CELL:
0824021281</td><td colspan="2">E-MAIL:jessm1@mweb.co.za</td><td>FAX:</td></tr>
<tr><td colspan="5">DEGREE FOR WHICH PROTOCOL IS BEING SUBMITTED: MMed PSych</td></tr>
<tr><td colspan="5">PART-TIME OR FULL-TIME: Full time</td></tr>
<tr><td colspan="2">FIRST REGISTERED FOR THIS DEGREE:</td><td colspan="2">TERM : 1</td><td>YEAR: 2016</td></tr>
<tr><td colspan="5">DEPARTMENT: Psychiatry</td></tr>
<tr><td colspan="5">TITLE OF PROPOSED RESEARCH:
A retrospective review of the efficacy of Tara Hospital's inpatient eating disorders programme in addressing physical, behavioural, psychological, and psychosocial symptoms</td></tr>
<tr><td colspan="4">CANDIDATE'S SIGNATURE:</td><td>DATE: 11 Oct 2018</td></tr>
<tr><td colspan="4">SUPERVISOR 1 (NAME & SURNAME): Dr Megan Jones</td><td>% Supervision 100%</td></tr>
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SYNOPSIS OF RESEARCH:

1. The broad aim of this study is to investigate the investigate the efficacy of Tara Hospital's inpatient EDU on various physical, behavioural, psychological, and psychosocial indicators of eating disorder psychopathology. To capture relevant demographic and clinical data to characterise the study sample;

2. To compare the participants' admission and discharge parameters/scores on indices of physical health (weight, BMI, % minimum expected weight); behavioural and psychological measures of eating disorder psychopathology (EDE-Q); and psychosocial impairment secondary to the eating disorder (CIA); and

3. To identify clinical and demographic factors that predict better response to an inpatient admission (i.e. greater improvement in the parameters/scores outlined in (2)).

ETHICS PENDING: Y ETHICS APPROVED: (circle appropriate symbol)	IF Y SUPPLY ETHICS CLEARANCE No:

As supervisor, I confirm that I have read the protocol which has been submitted for assessment.

SIGNATURE OF SUPERVISOR/S:	……	……
SIGNATURE PG OFFICE STAFF ……	REGISTERED YES……..….. NO……..	STAMP

A retrospective review of the clinical efficacy of Tara Hospital's inpatient eating disorders programme in addressing physical, behavioural, psychological, and psychosocial symptoms

University of the Witwatersrand, Department of Psychiatry

MMed Research Report Proposal

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1. Introduction

Eating disorders are one of the more common health problems afflicting women in Western society today[1]. Eating disorders may be hard to treat with high relapse rates[1] and the course of the illness can be protracted with lifelong morbidity[2] and disability – and for some mortality – if not treated early and aggressively[3].

The majority of patients with eating disorders are managed in an outpatient setting[4,5], but certain individuals require inpatient management. Inpatient treatment is an expensive and labour-intensive alternative to outpatient care but can be necessary when patients become medically unwell or do not respond adequately to outpatient interventions[6].

1.1 Types of eating disorders

The Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-5)[5] describes a total of nine eating disorders, but the three most common clinically are Other Specified Feeding or Eating Disorder (OSFED), Bulimia Nervosa (BN), and Anorexia Nervosa (AN)[2].

Anorexia Nervosa is characterised by a persistent restriction of caloric and nutritional intake leading to significantly low body weight in the context of age, sex, developmental trajectory and physical health; intense fear of gaining weight or becoming fat or persistent behaviour that interferes with weight gain (even though noted to be of low weight); disturbance in the way one's weight or shape is experienced; undue influence of body shape and weight on self-evaluation; or persistent lack of recognition of the dire state of the low body weight[5]. There are two subtypes – restricting and binge-eating/purging subtypes based on the predominant maladaptive eating and weight-control behaviours identified[5].

Bulimia Nervosa is an illness in which there are recurrent episodes of binge eating (eating greater amounts than most persons would consume in the same time period) with a sense of lack of control during these episodes, with recurrent inappropriate compensatory behaviours in order to prevent weight gain such as self-induced vomiting, use of laxative/diuretics, and/or excessive exercise[5]. The binge eating and compensatory behaviours occur at least once a week for three months[5].

Other Specified Feeding or Eating Disorders (OSFED) include atypical eating disorders or presentations where the full criteria for AN or BN are not met, but there is nonetheless significant distress and functional impairment[5].

1.2 Core psychopathology

Fairburn and colleagues[7] propose that whilst the three main types of eating disorders (AN, BN, and atypical eating disorders) have distinctive clinical features, all are maintained and driven by similar psychopathology, and share many commonalities. This is known as the "transdiagnostic" view of eating disorders, and holds that AN, BN, and OSFED all share the following three criteria: (1) overvaluation of shape, weight and eating control; (2) persistent disturbance of eating habits / weight control behaviours; and (3) impairment of physical health or psychosocial functioning[7]. Patients frequently shift from one predominant presentation to another over time (diagnostic migration[2,8]) and, whilst at different times the

behavioural and physical symptoms may differ, the core psychopathology typically stays the same[5,7].

1.3 Risk factors for development

Risk factors identified for the development of an eating disorder are multifactorial, with socio-economic factors, societal pressures, genes, personality, self-esteem, and family dynamics all contributing in varying degrees[5,6,9]. The development of eating disorders is associated with predominantly a Western cultural milieu where leanness and restraint over food intake is valued and encouraged [5,10].

1.4 Course of illness

Often the precipitating factors around dissatisfaction with body weight/image lead to dieting – which becomes a perpetuating factor when the effects receive positive feedback from others and when the physiological consequences of restriction and restraint themselves reinforce some of the restricting and compensatory behaviours – and moreover also predispose binge eating[5,8,10]. De Galle[2] recognises that both AN and BN can have a chronic course (15% and 23% respectively). Mortality rates for AN have been reported as high as 8%[11], but some studies have also reported comparable mortality rates for AN and BN (± 4%) and a slightly increased mortality for supposedly the 'less severe' OSFED presentation.[12]

Poor prognostic factors for AN is older age of onset, bulimic symptoms, vomiting, somatic and psychiatric comorbidities (such as obsessive-compulsive personality disorder [5,14,15], and lower body mass index (BMI) on admission to inpatient treatment[16]. Vall and Wade[15] highlighted that lower weight and shape concerns were predictors of a better outcome. In BN, childhood obesity, certain personality elements and low self-esteem are described as poor prognostic factors[14,15]. OSFED incorporates presentations of both atypical / sub-diagnostic or AN and BN. They share similar prognostic co-morbidities with the fully-fledged conditions[17].

<u>Psychiatric comorbidities</u>

In patients with eating disorders there is a strong correlation with affective disorders in particular including depression, mood intolerance, and anxiety[5,8,10]. Salbach-Andrae[18] established the high co-morbidity with major depression and anxiety, with 73.5% of the patient group in their study, diagnosed with either of these conditions. Solmi and colleagues[19], however, recognized that depressive symptoms, anxiety, and poor interpersonal relationships may be a result of the effects of the eating disorder (both physiologically and socially) and hence hold that only once a minimum expected weight has been restored, and the patient is clinically stable, should underlying primary mood disorders be diagnosed.

Premorbid personality features such as obsessiveness, perfectionism, and low self-esteem are clearly reported[5,8,10,20]. The most common personality types in AN noted are obsessive compulsive, avoidant, and dependant, whilst borderline personality disorder features are more commonly found in bulimic patients and those with the binge-eating/purging subtype of AN.[20]

1.5 Epidemiology

According to Smink[21] the incidence in the United Kingdom (UK) between 1989 and 2012 for AN was 4.7 per 100 000 person-years; for BN 6.6 per 100 000 person-years; and for OSFED, little data were available expect for a Spanish study which reported incidence of 6.5/100 000 person-years from 1990 to 2000[22].

Worldwide the ratio of female to male patients with eating disorders is between 10 to 20:1[23], with onset of eating disorder pathology during adolescence most likely due to changes in body morphology, and hormonal changes such as shifts in leptin and oestrogen[24]. In Westernised countries, the eating disorder patient is stereotypically white, adolescent, and female. There is an increasing trend for eating disorders in minority groups, males, and non-white patients[25].

1.6 Inpatient versus outpatient treatment

Eating disorders can be successfully managed on both an inpatient and outpatient basis[26]. Szabo and Terreblanche[7] remarked that whilst treatment for eating disorders is often initiated on an outpatient basis, there are a number of occasions that warrant admission. This is often fraught with difficulties for the patient and the families who may be averse to hospitalization. Inpatient care offers not only physical rehabilitation but also an opportunity for psychological intervention. It is a recognised as invaluable in severely underweight patients especially when acknowledging that the mortality amongst anorexia patients is twice that of any other of psychiatric condition[2, 4, 27].

Inpatient psychiatric treatment gives several short-term medical benefits, including physical and nutritional rehabilitation and evaluation; provides relief to patient's family, and reduces compensatory behaviours[27]. It also provides an opportunity to initiate psychological intervention to address, inter alia, underlying problematic thinking and aversion to troubling or anxiety-provoking emotional states[5,8]. However, it is costly and resource intensive, and patients may need to be admitted for many months[28].

Inpatient care is typically indicated for patients with extreme weight loss (< 15% ideal body weight) and impaired psychosocial functioning, or for patients who have not responded to outpatient intervention[2]. The National Institute for Health and Care Excellence (NICE) guidelines[29] prefer not to use Body Mass Index (BMI) or weight threshold's but rather rapid weight loss, bradycardia, and other ECG changes as indicators of the need for inpatient management.

Outpatient programmes are recommended as first line and provide less costly services for medically and psychologically more stable and motivated patients[5, 8]. The core therapies are implemented here too, with the additional benefit of being able to utilise skills learnt within the patient's home environment[6]. According to the TOuCAN Study in the United Kingdom, with five year follow up of patients, inpatient programmes are not necessarily more clinically effective than outpatient programmes[30]. However, specialist management is noted to be significantly more beneficial than primary care using registrar or medical oficers[30].

1.7 Psychotherapeutic approaches

Psychotherapy is typically a core component of all inpatient or outpatient treatment programmes[6]. Studies describe specific forms as being more efficacious in the different subtypes of eating disorders. Enhanced Cognitive Behaviour Therapy (CBT-E), an adapted form

of CBT for eating disorders, is often considered the treatment of choice for adult outpatients with BN[31], and has also shown good results for the treatment of AN,BN, and OSFED, in adults and adolescents, in a specialised inpatient setting[16]. Interpersonal therapy (IPT) has also been used successfully with adult outpatients with BN[31]. Family Based Therapy (FBT) is generally the recommended treatment for outpatient adolescents (and possibly young adults) with AN (and maybe also BN)[32]. There is currently no treatment of choice for adult outpatients with AN[16], although CBT-E and various interpersonal and psychodynamic approaches have shown some efficacy[2]. 1.8Predictors of response to intervention

Ba and colleagues[26] illustrated that early exit from a treatment programme is problematic, and is typically associated with poorer outcome. Pike[33] similarly reports than non-completers were less likely to manage on their own, and often showed rapid relapse of symptoms. Fichter and Quadflieg[34] reviewed the six-year outcome after inpatient programme completion, and showed that low body weight on discharge predicted unfavourable outcomes. Baran and colleagues[35] also linked low weight on discharge to increased risk for rehospitalisation.

Better outcomes are associated with higher motivation, higher self-esteem, and the admission of hunger during admission[14]. Adolescents generally have a better outcome than adults – possibly due to earlier diagnosis (often within a year of emergence of symptoms)[36]. An early age at onset, shorter duration of treatment, no relapses, higher socioeconomic levels, and higher level of education were all predictors of better outcome[35,36]. In the TOuCAN Study, lower levels of self-reported eating psychopathology at baseline was also a notable predictor of worse long-term outcome[30].

1.8 Eating Disorders in South Africa

A small number of studies have been conducted in South Africa on eating disorders. However, the actual incidence of eating disorders in this country is not known[9]. One of the earliest studies was done by Nash and Colburn between 1979 and 1989 [37.] .They reviewed the patients admitted to an inpatient unit in Cape Town over 10 years and described the demographics, which were in keeping with International findings.

Laxton[11] reported factors which influence body image in adolescents from Gauteng – noting that here again South African data show similarities with that found internationally.

Being so culturally varied, South Africa lends itself to research orientated towards the varied eating disordered pathology across the demographic and racial groups. Visser et al[38] engaged with the eating attitudes of adolescent girls attending a traditional Jewish high school in Johannesburg – and reported that the rates of eating disordered thinking in this group were higher that seen in other similar cohorts. Edwards and Molden[39] reviewed bulimic eating patterns in black university students in the Eastern Cape. Of importance was that it showed more variation across demographic than racial groupings – but did illustrate that black patients who exhibited bulimic behaviours described less shame and negative self-evaluation that their white counterparts.

Szabo and Hollands[24] described the increasing prevalence of eating disorder attitudes in a specific group of black adolescents in Johannesburg – citing here that an increasing Western influence is impacting the development of eating disorders in this previously lower-risk group. Szabo and Morris[40] reviewed the impact of "Westernised" pressures around body image, on adolescents in high schools within Kwa-Zulu Natal. It can be stressed that the adolescent group here – with a mix of traditional and cultural rituals around social over - eating blended with westernised ideals –makes it a high risk group for development of eating disorders. Le Grange et al [41] illustrates further challenges when reviewing the concept of starvation amongst impoverished patients in South Africa.

Mchiza et al[42] reviewed the correlation between the body image and methods of weight control in a cohort of South Africans older than 15 years. It was noted that a high percentage had a distorted body image, and that in those that were dissatisfied only 12% made attempts to rectify this through dietary changes and exercise. The EAT questionnaire has been used repeatedly in South African studies. Szabo, Allwood [43] applied the EAT 26 test in a rural Zulu speaking adolescent population, and noted that whilst the validity of the test in this group needed to be considered – there is clearly a lower risk for development of eating disorder in a rural population group. Szabo, Hollands [24] reviewed the abnormal eating attitudes in high-school girls in a community setting. The EAT-26 was utilised here – and indicated a clear developmental continuum from grade 9 onwards.

1.9 Studies at Tara Hospital

Tara Hospital's EDU has been the site for a total of 4 studies into eating disorders to date although, because the programmes that have been implemented in the EDU have varied over the years and the changes and timing thereof poorly recorded, direct comparison of studies is challenging. Prior to 2003, Tara ran two separate programmes in separate wards (Anorexic Ward and Bulimic Ward), whereas thereafter patients with AN, BN, and OSFED were treated within the same ward, although on separate programmes within the ward (described above). In late 2014, the "Bulimic Programme" shifted from being six-weeks and substantially different to the "Anorexic Programme", to the now minimum 13-week programme which is roughly comparable to the programme used to treat underweight patients (described above).

The demographics of ED patients admitted Tara have been examined across different periods: Norris[6] (1976 – 1978; n = 54; 8 bedded unit), Szabo and Gabriel [25] (1987 – 1996; n = 254; anorexic unit), Vahed[45] (2001 – 2002; n = 59; only anorexic patients studied), Abrie[47] (2005 – 2008; n = 42; only anorexic patients studied). All studies reported that Tara inpatients were mainly Caucasian, single, younger than 40, and female, although Szabo and Gabriel [25] reported a trend for increasing age and decreasing socioeconomic class of admitted patients over time (comparing findings with earlier reviews of patient demographics).

A few studies have also looked specifically at the change in the race and gender of patients admitted to Tara's EDUs over time [6,9, 25, 45, 47,46]. Szabo and Gabriel[25] reported in their 10-year study (1987 – 1996) of admissions to Tara's EDU that there were no non-white patients (and very few males) admitted in the study period. In contrast, between 1998 and 2004, Delport and Szabo[9] found that with more recent admissions, there was an increase in non- white and

male admissions. Freeman and Szabo [4] reviewed specifically eating disorders in males admitted to the EDU at Tara between 1993-2002. It reported patients presented from higher socio-economic classes with significant over-exercising as a compensatory mechanism. .

Vahed's[45] study also looked specifically at the different characteristics in patients admitted for the different subtypes of AN, finding that 45% of admitted patients with AN had the restricting subtype and the majority suffered with the binge-purge subtype.

Abrie's[46,47] research also examined factors which predicted completion vs non-completion of the inpatient programme: factors predicting a lower likelihood of programme completion included previous substance use, Caucasian ethnicity, and certain personality traits (description of oneself as engaging in self-destructive behaviour, or being unnecessarily dependant), and unemployment / being a scholar with unemployed parents.

Green and Szabo[48] conducted research into the effect of a resistance training programme during weight restoration findings showed improvements in body composition (more lean mass), psychological wellbeing[48] as well as strength. Similar benefits in strength and flexibility were seen by Chantler et al [44] with an 8 -week exercise programme implemented in the EDU for appropriate patients.

There is to date only one study in the unit which has reviewed the efficacy of the programme itself[7]. Szabo and Terreblanche[7] conducted a study reviewing the efficacy of the Tara inpatient unit between November 1993 and October 1995. Psychological intervention was in the form of individual cognitive behavioural therapy, and group and family therapies. The study used the changes in the Eating Disorders Inventory (EDI-1) to locate eating disorder beliefs, attitudes and behaviours and the Beck's Depression Scale to review changes in mood. It was concluded that there were significant improvements in the psychological, nutritional, and emotional functioning on discharge form the unit, and noted a correlation between low BMI and subjective depression on admission.

1.10 Tara Hospital's Eating Disorders Unit (EDU)

Currently, and for the proposed study period, the Eating Disorders Unit (EDU) at Tara Hospital (specialized psychiatric hospital in Sandton, Johannesburg) admits up to eight patients at a time with AN, BN, or OSFED who are too unwell for outpatient treatment or for whom outpatient care has failed. The unit receives referrals from throughout South Africa and neighbouring countries, and admits patients who are 13 years or older. (Younger eating disorder patients requiring inpatient care are admitted to the Children's Ward.)

Patients are admitted as either voluntary, assisted, or involuntary patients, depending on their age and the illness severity. The aim of admission is to re-establish a healthy weight through weight restoration and/or to facilitate weight maintenance; to stabilise eating patterns; to limit or stop compensatory behaviours; and to address the core psychopathology of the ED (e.g. over-evaluation of shape and weight and marginalisation of other important life areas). Patients are treated in a multidisciplinary team, including nurses, psychiatry staff, an occupational therapist, dieticians, clinical psychologists, and a social worker [25]. There is also a

school on the property which school-going patients attend when they are sufficiently well. The primary psychotherapy intervention since 2008 has been CBT-E.

The unit runs two very similar programmes, which each comprise six stages. The first programme focuses on weight restoration, and the second programme focusses on weight maintenance (see Appendix A and B). (The primary difference between the programmes is that on the first programme only, patients need to meet weight restoration targets in order to move up a stage, whereas on the second programme this criterion is absent because the goal is weight maintenance.) As patients progress through the stages, they are required to assume increasing responsibility for their eating and compensatory behaviours and are progressively granted longer leaves of absence from the programme to 'practice' in the home environment. Length of stay is a minimum of 13 weeks, although can be significantly longer for patients who are very underweight on admission and who require a lengthier stay to reach their minimum expected healthy weight range.

Study Aims and Objectives

The broad aim of this study is to investigate the clinical efficacy of Tara Hospital's inpatient EDU programme between November 2014 and January 2019 on various physical, behavioural, psychological, and psychosocial indicators of eating disorder psychopathology. The three main objectives are:

a. To capture relevant demographic and clinical data to characterise the study sample;
b. To compare the participants' admission and discharge parameters/scores on indices of physical health (weight, body mass index (BMI), % minimum expected weight); behavioural and psychological measures of eating disorder psychopathology (Eating Disorder Examination Questionnaire (EDE-Q); and psychosocial impairment secondary to the eating disorder (Clinical impairment Assessment CIA); and
c. To identify clinical and demographic factors that predict better response at discharge to an inpatient admission (i.e. greater improvement in the parameters/scores outlined in (2)).

Methods

3.1 Setting

The study will be conducted at Tara, the H. Moross Centre, within the hospital's inpatient EDU (Ward 1&2).

3.2 Tara's EDU programme

The programmes being run during the proposed study time period are described in the Introduction. The minimum expected weight for adults (18 years and above) is calculated based on a Body Mass Index (BMI) of 20kgm^{-2}, with the maximum healthy weight set at a BMI of 24,9kgm^{-2}. Occasionally, for patients who are not of reproductive age and who have had a chronic course, the team may aim for a slightly lower BMI of between 18.5kgm^{-2} and 19kgm^{-2}. The minimum expected weight for adolescents (17 years and younger) is calculated based on the 50th percentile BMI for a similarly aged child (CDC growth charts).

Depending on the patient's weight on admission and food intake prior to admission, the patient is generally started on between 800kcal and 1500kcal, and the calories are adjusted to obtain a weight gain or between 750g and 1,5kg per week (weight restoration phase) or to allow for weight maintenance (weight maintenance phase).

3.3 Study procedure

This study will comprise a retrospective review of files over a four-year period for all patients admitted to the EDU after November 2014 and discharged before end January 2019. The type of study design is thus a quasi-experimental pre- and post-repeated measures programme evaluation. Participants' inpatient files will be reviewed to collect demographic and clinical information and rating scale scores.

3.4 Participants

Study participants will include patients admitted and discharged between November 2014 and January 2019 respectively. Exclusion criteria will include: (1) not meeting diagnostic criteria for AN, BN, or OSFED (e.g. patients admitted for refeeding secondary to a suspected medical condition) and (2) missing files.

3.5 Data collection

The following demographic and clinical information will be collected from the patients' files: date of birth (to calculate age on admission); gender; race; home language; languages spoken; marital/relationship status; highest level of education; employment status prior to admission; weight, height, BMI, and % of minimum expected weight on admission and discharge; average rate of weight gain (kg/week) in weeks preceding reaching minimum expected weight; maximum calorie intake; source of referral (clinician, geographical area, state/private); length of admission (days); number of previous admissions to Tara's EDU; number of previous admissions to other EDU facilities; number of previous medical admissions for ED treatment; mental health care status (involuntary, assisted, or voluntary) on admission and discharge and during course of the programme; previous or current co-morbid psychiatric, substance, and medical diagnoses; duration of ED; age of onset of ED; type of eating disorder on admission (AN-R; AN-BP; BN; OSFED); previously diagnosed EDs (AN-R; AN-BP; BN; OSFED); psychiatric and other medications; and whether the patient completed the programme, was discharged prematurely by the team, was transferred to another programme or hospital, or RHT-ed (including reasons therefore).

The scores and subscale scores for the two rating scales administered at the start and end of each programme will be recorded. These are described below:

3.6 Rating scales

The Clinical Impairment Assessment (CIA) Questionnaire and Eating Disorder Examination Questionnaire (EDE-Q) are performed in the week of admission and in the last few days prior to discharge to evaluate changes in functioning. Worldwide, programmes that used CBT-E typically use the EDE-Q and CIA to measure improvements across treatment[35]. These rating scales have been used in the programme since November 2014. (Other rating scales such as the EDI had been used intermittently before this[4] but were discontinued after the EDE-Q and CIA were introduced.)

The EDE-Q reviews the psychopathology behind the development of an eating disorder and in doing so reviews the driving force behind the maladaptive behaviours. The CIA is a disorder specific review of the impairment experienced as a result of the condition[49]. Both measures are self-report scales and are written in English (or very occasionally in Afrikaans). Neither has been validated in the South African context.

a) Eating Disorder Examination Questionnaire 6.0 (EDE-Q 6.0) (Appendix C)

The EDE-Q has been widely used in international studies[50]. It is the self-report version of the clinician-administered Eating Disorder Examination (EDE). The EDE is the gold standard, but the EDE-Q was developed as the former proved to be too time consuming and with possible clinician bias. The EDE-Q comprises 28 items focussing on symptom occurrence in the preceding 28 days, and reviews the four different domains core to ED psychopathology: restraint (5 items), eating concern (5 items), shape concern (5 items), weight concern (8 items), and provides one global score ([sum of subscale scores]/4). Scores of four or higher are considered to be within the clinical range[19] – with higher scores indicating higher psychopathology severity or frequency[35]. There are an additional six items (not included within global or subscale score calculations) which assess the frequency of bingeing and compensatory behaviours. The EDE-Q has good psychometric properties and is often used to measure response to treatment[10]. It demonstrates acceptable levels of internal consistency for its global and subscale scores, good concurrent validity with the EDE[50], and satisfactory test-retest reliability[119].

b) The Clinical Impairment Assessment (CIA) [17] (Appendix D)

The CIA was developed to assess the impact that eating disorders would have on all areas of psychosocial functioning. This is an illness-specific self-reporting questionnaire which follows the Likert 4-point format like the EDE-Q, reviewing the impact the main areas of psychopathology in eating disorders has on impairment [36]. It has a similar structure to EDE-Q, relating to the previous 28 days, and is designed for co-administration with the EDE-Q. It is a brief questionnaire with 16 different items reviewing four specific domains of life where impairment can be identified (mood and self-perception; cognitive functioning, interpersonal functioning, work performance). Each item is scored (0, not at all, to 3, a lot), and then a single global score is given which ranges between 0 and 48. The higher the score the greater the impairment. A global score above 16 indicates significant impairment [51]. Reviews indicate the CIA shows good test-retest reliability, construct validity, and sensitivity to change, and hence is used widely in research models worldwide[17].

3.7 Sample size

The sample size is limited by the available data i.e. patients admitted in the defined study period and not meeting any of the exclusion criteria. The anticipated sample size is around 60 patients.

Data Analysis

The data which describe the sample, that is, the demographic and clinical characteristics of the study sample, will be generated first. This will be done in the form of means for continuous variables (for example, age) and frequencies and percent distributions for categorical data (for example, source of referral). This part of the analysis will be done in order to understand the sample of patients that will be involved in the study. In addition, reliability information regarding the data collection instruments will be generated. In this regard, the researcher will compute the Cronbach Alpha to measure the reliability of the four different domains core to psychopathology in the Eating Disorder Examination Questionnaire (EDE-Q) as well as the four specific domains of life where impairment can be identified in the Clinical Impairment Assessment Questionnaire (CIA). In addition, a composite Cronbach Alpha will be computed distinctly for the EDE-Q and CIA questionnaires.

Reliability analysis will allow the researcher to study the properties of measurement scales and the items that compose the scales. The Cronbach Alpha calculates a number of commonly used measures of scale reliability and also provides information about the relationships between individual items in the scale[52]. The Cronbach Alpha values range between 0 and 1 and are a model of internal consistency based on the average inter-item correlation. The higher the score, the more reliable the generated scale. Nunnaly[53] has indicated 0.7 to be an acceptable reliability coefficient. This component of the analysis will answer objective 1 of the study.

The analysis that will be conducted in order to answer objective 2 is now provided.

First, descriptive statistics (mean, median, standard deviation, interquartile range, skewness and kurtosis) will be calculated in respect of the study participants' admission and discharge parameters/ scores as regards physical health, behavioural and psychological measures of eating disorder psychopathology (EDE-Q) and psychosocial impairment secondary to the eating disorder (CIA). The calculation of the mean, median and standard deviations will be done in order to understand the standing of the study sample on the various demographic and clinical variables of interest. In particular, skewness and kurtosis will be used to measure the distribution and normality of the data. The researcher will apply appropriate statistical tests if the data is either normally distributed or if it is found to be skewed. These tests are specified in the upcoming respective sections.

Second, multivariate correlations between dependent and independent variables of interest will be conducted to further meet the expectations of the second objective of this study. In this regard, the researcher will use the Pearson's correlation to determine the association between continuous variables, that is, physical health and behavioural and psychological measures of eating disorder psychopathology (EDE-Q) and psychosocial impairment secondary to the eating disorder (CIA). In the same vein, the association between categorical variables, for example, clinical variables such as MHC status and demographic factors such as sex, will be analysed using the Pearson's chi-squared (X^2) test. The statistical significance of the Pearson's correlation and the Pearson's chi-squared test will be determined at the level of $p<0.05$.

Third, in support of multivariate analysis, if the data is normally distributed, the researcher will use the parametric Paired Samples *t*-test to compare the mean scores/ indices of the study sample with respect to admission and discharge variables of interest for EDE-Q and CIA measurements. However, if the data is not normally dispersed the researcher will use the non-parametric Friedman's 2-way ANOVA by ranks test. For independent samples with two groups, if the data is normally distributed, the researcher will use the parametric Independent Samples *t*-test. If the data is not normally distributed the researcher will use the non-parametric Mann-Whitney test. The statistical significance of difference for these tests will be determined at the level of $p<0.05$.

Fourth, if the data is normally distributed, the researcher will perform additional multivariate analysis using the parametric one-way analysis of variance (ANOVA). The parametric one-way analysis of variance test will be used to compare the mean scores of three or more groups in the study sample, for example, categorisations by marital status, employment status and racial grouping. If the data is not normally distributed the researcher will use the non-parametric Kruskall-Wallis test. The statistical significance statistic will indicate whether homogeneity exists or alternatively if the groups differ. The researcher will note that the differences will be statistically significant if the *p*-values are below 0.05.

Finally, in order to provide analysis that answer objective 3, the researcher will perform multivariate binary logistic regression analysis to ascertain the clinical and demographic factors that predict better response to an inpatient admission (that is, greater improvement in the parameters/scores/indices regarding physical health, behavioural and psychological measures of eating disorder psychopathology (EDE-Q) and psychosocial impairment secondary to the eating disorder (CIA). Three multivariate statistical models will be constructed in order to show the differential impact of the variables in the two categories constituting the various independent variables (clinical and demographic factors) on the dependent variable (better response to an inpatient admission). The statistical significance of difference for the Odds Ratios (OR) in the multivariate binary logistic regression models will be tested at the level of $p<0.05$.

3.9 Ethics

Only data for patients who have provided written informed consent for their files to be used in retrospective reviews will be included in the study. The site utilizes specialized consent process whereby patients and their parent/caregiver's provide consent at the point of admission allowing for utilization of clinical information for research purposes. Data collected during the research will remain confidential – names and identifying details will be known only to the primary researcher (Dr Jess Meddows-Taylor) and her supervisor (Dr Megan Jones) and will be disguised when presenting the data in the dissertation, at professional conferences, or in an academic journal. Ethics clearance will be obtained from the Wits Medical Ethics Committee and the Tara Hospital Research Committee, with a National Health Research Database (NHRD) number before commencement of the study.

An application for Ethics approval will be submitted.

d. Timing

Gant graph

	Oct	Nov	Dec	Jan	Feb	March	April	May
Protocol development	X	X	X	X	X			
Ethics application							X	
Collecting data							X	X
Data analysis								X
Write up of report begins								

e. Funding

The costs for this study are negligible and the researcher will absorb any miscellaneous expenses incurred. A personal computer will be used for data analysis.

f. Problems/limitations

- The sample size is wholly dependent on the number of individuals admitted in the defined period and who have completed the rating scales.
- The rating scales used have not been validated for use with the South African population.
- Patients may answer rating scales less than truthfully.
- Outcome measures are only assessed upon discharge (i.e. immediate outcomes), and not again at a later time point to assess whether improvement is sustained after discharge.

Programme !	1A	1B	1C	1D	1E	1F
Weight	≥ 25% underweight	< 25% underweight	< 20% underweight	< 15% underweight	< 10% underweight	< 5% underweight
Time up	Patient to remain seated or lying down *in the dormitory* except when walking to and from scheduled ward activities, the bathroom, and when showering/bathing (once daily)	Patient to remain seated or lying down *in the dormitory* for one hour after meals and 30 minutes after snacks, except if attending ward activities; patient may relax in the outdoor area		No restrictions on time up in the dormitory or outdoor area		
Eating location	All meals and snacks eaten under supervision in ED dining room			Lunch unsupervised in dormitory; other meals and snacks in ED dining room	Breakfast and Lunch unsupervised in dormitory; other meals and snacks in ED dining room	All meals unsupervised in dormitory; snacks in ED dining room
Dishing up of meals*	All meals dished up by staff		Lunch (Supper if school-going) dished up by patient under supervision	Breakfast and Lunch (Supper if school-going) dished up by patient under supervision	All meals dished up by patient under supervision	
Nurse therapy	1 x 45-minute session per week (nurse will fetch patient from dormitory)		1 x 45-minute session per week (patient to arrive independently for session)			
Individual therapy	2 x 45-minute sessions per week (therapist will fetch patient from dormitory)		2 x 45-minute sessions per week (patient to arrive independently for sessions)			
Psychology groups	Interpersonal Group When stable, patient may be considered for Art Therapy	Interpersonal Group and Art Therapy				
Dietetics	Individual sessions approximately weekly		Individual sessions approximately weekly, Dietetics Group, and OT/Dietetics Group			
Occupational therapy	Relaxation and Personal Management Groups When stable, patient may be considered for Life Skills Groups	Relaxation, Personal Management, and Life Skills Groups; Yoga	Full attendance of Occupational Therapy groups (including Coffee Shop, and OT/Dietetics Group)			
School / University / Work	Nil	Work may be done on the bed, preferably reading books	If school-going, attendance of Tara School		If school-going, attendance of Tara School Patient may gradually start attending her home school or University, or returning to work	
Walks	No walks		10-minute unsupervised walk once weekly**	10-minute unsupervised walk twice weekly**	10-minute unsupervised walk thrice weekly**	10-minute unsupervised walk thrice weekly** During visiting times, patient may leave the ward (but not Tara premises) for 30 minutes with a responsible adult**
Exercise	After patient reaches her minimum expected weight: 2 x 30-minute supervised exercise sessions and 1 x 30-minute unsupervised exercise session per week**					
Time out	No time out		1 snack out over the weekend	1 day out over the weekend, missing 1 meal and 2 snacks	1 afternoon/evening out during the week, missing 1 meal and 1 snack (individual or group therapies may not be missed)*** 1 night out over the weekend, missing 2 meals and 2 snacks	1 afternoon/evening out during the week, missing 1 meal and 1 snack (individual or group therapies may not be missed)*** Full weekend out leaving on Friday after Lunch and returning on Sunday before 19h30

Appendix A - **Programme 1** (Ward 1&2 Eating Disorders Unit)

* All snacks are dished up by staff

**Adult patients are to sign out with nurses for walks and unsupervised exercise sessions; patients less than 18 years must always be supervised by staff for walks and exercise sessions

*** Weekday time out may be combined with weekend time out if it cannot be taken during the week.

The multidisciplinary team (MDT) may adapt the programme to cater for the needs of individual patients.

Criteria for moving up a stage: Meeting minimum weight expectation for the next stage; stage-appropriate progress in challenging behaviour related to the eating disorder; participation in all therapeutic activities; adherence to the rules; and completing a *minimum* of two weeks on the previous stage.

	2A	2B	2C	2D	2E	2F
Time up	Patient to remain seated or lying down *in the dormitory* except when walking to and from scheduled ward activities, the bathroom, and when showering/bathing (once daily)	Patient to remain seated or lying down *in the dormitory* for one hour after meals and 30 minutes after snacks, except if attending ward activities; patient may relax in the outdoor area		No restrictions on time up in the dormitory or outdoor area		
Eating location	All meals and snacks eaten under supervision in ED dining room			Lunch unsupervised in dormitory; other meals and snacks in ED dining room	Breakfast and Lunch unsupervised in dormitory; other meals and snacks in ED dining room	All meals unsupervised in dormitory; snacks in ED dining room
Dishing up of meals*	All meals dished up by staff		Lunch (Supper if school-going) dished up by patient under supervision	Breakfast and Lunch (Supper if school-going) dished up by patient under supervision	All meals dished up by patient under supervision	
Nurse therapy	1 x 45-minute session per week (nurse will fetch patient from dormitory)		1 x 45-minute session per week (patient to arrive independently for session)			
Individual therapy	2 x 45-minute sessions per week (therapist will fetch patient from dormitory)		2 x 45-minute sessions per week (patient to arrive independently for sessions)			
Psychology groups	Interpersonal Group When stable, patient may be considered for Art Therapy	Interpersonal Group and Art Therapy				
Dietetics	Individual sessions approximately weekly	Individual sessions approximately weekly, Dietetics Group, and OT/Dietetics Group				
Occupational therapy	Relaxation and Personal Management Groups When stable, patient may be considered for Life Skills Groups	Full attendance of Occupational Therapy groups (including Yoga, Coffee Shop, and OT/Dietetics Group)				
School / University / Work	Nil	If school-going, attendance of Tara School			If school-going, attendance of Tara School Patient may gradually start attending her home school or University, or returning to work	
Walks	No walks		10-minute unsupervised walk once weekly**	10-minute unsupervised walk twice weekly**	10-minute unsupervised walk thrice weekly**	10-minute unsupervised walk thrice weekly** During visiting times, patient may leave the ward (but not Tara premises) for 30 minutes with a responsible adult**
Exercise	After patient reaches her minimum expected weight: 2 x 30-minute supervised exercise sessions and 1 x 30-minute unsupervised exercise session per week**					
Time out	No time out		1 snack out over the weekend	1 day out over the weekend, missing 1 meal and 2 snacks	1 afternoon/evening out during the week, missing 1 meal and 1 snack (individual or group therapies may not be missed)*** 1 night out over the weekend, missing 2 meals and 2 snacks	1 afternoon/evening out during the week, missing 1 meal and 1 snack (individual or group therapies may not be missed)*** Full weekend out leaving on Friday after Lunch and returning on Sunday before 19h30

Appendix B **Programme 2** (Ward 1&2 Eating Disorders Unit)

* All snacks are dished up by staff

**Adult patients are to sign out with nurses for walks and unsupervised exercise sessions; patients less than 18 years must always be supervised by staff for walks and exercise sessions

***Weekday time out may be combined with weekend time out if it cannot be taken during the week

The multidisciplinary team (MDT) may adapt the programme to cater for the needs of individual patients

Criteria for moving up a stage: Stage-appropriate progress in challenging behaviour related to the eating disorder; participation in all therapeutic activities; adherence to the rules; and completing a *minimum* of two weeks on the previous stage.

Remember: Please speak to staff if you are struggling to manage your emotions or thoughts, or to contain your urges to engage in behaviour related to the eating disorder or any other self-destructive behaviour. Being sufficiently brave to admit to difficulties or to ask for support does not necessarily mean that you will be held back a stage: on the contrary, it's usually a sign of significant progress.

Appendix C

Eating Disorder Examination Questionnaire

This questionnaire only includes questions concerning the last 4 weeks (28 days)
Please read **all the questions carefully** and answer all the questions truthfully. Many thanks!

Questions 1-12: Please circle the number that describes your behaviour the best.
Please remember that this questionnaire includes questions concerning the last 4 weeks (28 days) only.

	No Days	*Days 1-5*	*Days 6-12*	*Days 13-15*	*Days 16-22*	*Days 23-27*	*Every Day*
1.Have you purposefully tried to eat less, to change your shape or lose weight?	*0*	*1*	*2*	*3*	*4*	*5*	*6*
2.Have you not eaten the entire day (8 hours or longer) to change your shape or lose weight?	*0*	*1*	*2*	*3*	*4*	*5*	*6*
3.Have you tried not eating food which you normally enjoy eating to change your shape or lose weight?	*0*	*1*	*2*	*3*	*4*	*5*	*6*
4.Have you tried to stick to strict dietary rules in order to change your shape or lose weight? For example eating only a specific type of food or a certain amount of food or a food with a certain amount of calories	*0*	*1*	*2*	*3*	*4*	*5*	*6*
5.Did you aim to have an empty stomach completely empty of food?	*0*	*1*	*2*	*3*	*4*	*5*	*6*
6.Did you aim to have a completely flat stomach?	*0*	*1*	*2*	*3*	*4*	*5*	*6*
7.Do you constantly think about food or calories that you struggle to concentrate on ordinary tasks, such as (watching TV, reading or computer games)?	*0*	*1*	*2*	*3*	*4*	*5*	*6*
8.Do you constantly think about your shape or losing weight that you struggle to concentrate on ordinary tasks, such as (watching TV, reading or computer games?)	*0*	*1*	*2*	*3*	*4*	*5*	*6*
9.Do you worry about losing control over food (Fear that once you start eating you might not be able to stop?)	*0*	*1*	*2*	*3*	*4*	*5*	*6*
10.Do you worry about gaining weight?	*0*	*1*	*2*	*3*	*4*	*5*	*6*
11.Do you feel over-weight or fat?	*0*	*1*	*2*	*3*	*4*	*5*	*6*
12.How often to you think about/dream about losing weight?	*0*	*1*	*2*	*3*	*4*	*5*	*6*

<u>Questions 13-18:</u> Please fill in the number of times the following questions is relevant to you and best describes your behaviour in the past four weeks (28 days) These questions pertain to the thought of "losing control over eating".
Please remember that this questionnaire includes questions concerning the last 4 weeks (28 days) only.

13. How many times in the past 28 days have you eaten a portion of food that other people in your situation would think of as "big"?	.....
14. In how many of your situations to you feel like you are losing control over eating?	.....
15. How many times in the past 28 days have you eating a really big meal and then felt as if you were losing control of eating?	.....
16. How many times in the past 28 days have you managed to make yourself vomit?	.....
17. How many times in the past 28 days have you taken laxatives in order to change your shape or lose weight?	.....
18. How many times in the past 28 days have you exercised excessively to change your shape or lose weight? (not just exercised for fun)	.....

<u>Questions 19-21:</u> Please circle the number that describes your behaviour the best.
Please remember that this questionnaire includes questions concerning the last 4 weeks (28 days) only.
These questions are about the thought of eating a portion of food that other people in your situation would think of as "big" as well as the feeling of "losing control over food".

	No days	Day 1-5	Day 6-12	Day 13-15	Day 26-22	Day 23-27	Every Day
19. How many days in the past 28 days have you secretly eaten something?	0	1	2	3	4	5	6
20. How often in the past 28 days have you felt guilty over the food you ate in the fear that the amount of food you ate would change your figure or make you gain weight?	0	1	2	3	4	5	6
21. How many times in the past 28 days have you felt anxious when other people were watching you eat?	0	1	2	3	4	5	6

<u>Question 22 – 28:</u> Please circle the number that describes your behaviour the best.
Please remember that this questionnaire includes questions concerning the last 4 weeks (28 days) only.

These questions pertain to your “weight “(by what you see on the scale) and your “figure”

	No days	Day 1-5	Day 6 -12	Day 13-15	Day 26-22	Day 23-27	Every Day
22. Does your weight influence how you feel about yourself as a person?	0	1	2	3	4	5	6
23. Does your figure influence how you feel about yourself as a person?	0	1	2	3	4	5	6
24. How much anxiety would it cause you if someone asked you to weigh yourself once a week in the next four weeks (not more not less)	0	1	2	3	4	5	6
25.How unhappy are you about your weight?	0	1	2	3	4	5	6
26.How unhappy are you about your figure?	0	1	2	3	4	5	6
27.How unhappy or embarrassed do you feel when you see yourself naked in the mirror or look at yourself in the reflection of a shop window or need to get undressed before taking a bath or shower?	0	1	2	3	4	5	6

(by what you see in the mirror).

Appendix D

CLINICAL IMPAIRMENT ASSESSMENT QUESTIONNAIRE (CIA 3.0)

Instructions

Please place an 'X` in the column which best describes how your eating habits, exercising or feelings about your eating, shape or weight have affected your life over the past 4 weeks (28 days). Thank you.

	Over the past 28 days, to what extent have your eating habits, exercising or feelings about your eating, shape or weight…….	**Not at all**	**A little**	**Quite a bit**	**A lot**
1	… made it difficult to concentrate?				
2	… made you feel critical of yourself?				
3	…stopped you going out with others?				
4	…affected your work performance (if applicable)?				
5	…made you forgetful?				
6	…affected your ability to make everyday decisions?				
7	…interfered with meals with family or friends?				
8	…made you upset?				
9	…made you feel ashamed of yourself?				
10	…made it difficult to eat out with others?				
11	…made you feel guilty?				
12	…interfered with you doing things you used to enjoy?				
13	…made you absent-minded?				
14	…made you feel a failure?				

15	…interfered with your relationships with others?				
16	…made you worry?				

Appendix E

Data Collection Sheet

Clinical Data

1. **Hospital File:**
2. **File number in study:**
3. **Source of referral:**
   Private/ govt:
4. **Source of referral:**
   Province:
5. **Date of admission:**
6. **Date of discharge:**
7. **Duration of pre-admission illness:**
8. **Length of admission (days):**
9. **Diagnosis:**
10. **Reason for discharge: if RHT provide reason:**
11. **Previous admission? place, date, number, duration of previous admission:**
12. **Weight on admission (kg):**
13. **Weight on discharge (kg):**
14. **Height on admission (m):**
15. **Height on discharge (m):**
16. **BMI on admission:**
17. **BMI on discharge:**
18. **Minimum expected weight (kg) on admission:**
19. **Minimum expected weight (kg) on discharge:**
20. **% under minimum expected weight on admission:**
21. **% under minimum expected weight on discharge:**

22. **Rate of weight gain (kg/week) until MEW reached:**

23. **Maximum calorie intake:**

24. **Programme completed- 1 or 2:**

25. **MHCU status:**

Demographic details:

26. **Date of birth:**

27. **Age (years/months):**

28. **Sex:**

29. **Racial group:**

30. **First language(s):**

31. **Languages spoken:**

32. **Marital/Relationship status:**

33. **Highest level of education:**

34. **Employment prior to admission:**

35. **Family history of eating disorder:**

36. **Family history of psychiatric disorders:**

37. **Co-morbid substance use – previous/ current:**

38. **Co-morbid medical conditions – previous / current:**

39. **Co-morbid psychiatric conditions – including personality disorders – previous / current:**

Questionnaires:

CIA on admission		**CIA on discharge**	
Total		Total	
Personal		Personal	
Cognitive		Cognitive	
Social		Social	
EDE-Q on admission		**EDE-Q on discharge**	

Total		Total	
Restraint		Restraint	
Eating concern		Eating concern	
Weight concern		Weight concern	
Shape concern		Shape concern	
No. of times felt out of control of eating		No. of times felt out of control of eating	
No. of times laxatives used No. of times excessively exercised		No. of times laxatives used No. of times excessively exercised	
No. of times binged		No. of times binged	
No of times purged		No of times purged	

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Appendix A1: Approval for change of title

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

23 July 2020
Person No: 8404716
TAB

Dr U Subramaney
P O Bx 10411
Vorna Valley
1686
South Africa

Dear Dr Subramaney

Jessica Meddows-Taylor: Change of title of research

This is to inform you that approval has been granted for Jessica Meddows-Taylor to change the title of his/her Research Report for the degree of **Master of Medicine** as follows:

From:

To: **a review of the clinical efficacy of an in-patient eating disorders programme**

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix B: Ethics Clearance Certificate Wits University

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Jessica Clair Meddows-Taylor

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M190660

NAME: (Principal Investigator)	Dr Jessica Clair Meddows-Taylor
DEPARTMENT:	Psychiatry Tara Hospital - The H. Moross Centre
PROJECT TITLE:	A Retrospective review of clinical efficacy of Tara Hospital's inpatient eating disorders programme in addressing physical, behavioural, psychological and psychosocial symptoms
DATE CONSIDERED:	28/06/2019
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Megan Jones
APPROVED BY:	Dr. CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	03/07/2019

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **June** and will therefore be due in the month of **June** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix C: Tara Ethics Clearance

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH

TARA the H. Moross Centre

Private Bag X7
RANDBURG 2125

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Ronelle.Price-Hughes@gauteng.gov.za

MEMORANDUM

TO: **DR F.A OTIENO – CEO TARA HOSPITAL**

CC: **DR T. MADIGOE – CLINICAL HEAD**

FROM: **DR. R. PRICE-HUGHES – CHAIRPERSON TARA RESEARCH COMMITTEE**

DATE: **18 JANUARY 2019**

SUBJECT: REQUEST FOR APPROVAL FOR DR JESSICA CLAIR MEDDOWS-TAYLOR TO CONDUCT RESEARCH AT TARA HOSPITAL
(NHRD PROPOSAL DETAILS: TBC)

1. Purpose

The purpose of the application is to request permission for Dr Meddows-Taylor to conduct research at Tara Hospital as part of her MMed in Psychiatry.

2. Background

The title of the study is "**A retrospective review of the clinical efficacy of Tara Hospital's inpatient eating disorders programme in addressing physical, behavioural, psychological, and psychosocial symptoms"** It is widely known that eating disorders are one of the most common health problems afflicting women in Western society today. The course of the illness can be protracted with lifelong morbidity and disability – and for some mortality - if not treated early and aggressively[2]. Unsurprisingly they are hard to treat with high relapse rates. Most patients with

2. To compare the participants' admission and discharge parameters/scores on indices of physical health (weight, BMI, % minimum expected weight); behavioural and psychological measures of eating disorder psychopathology (EDE-Q); and psychosocial impairment secondary to the eating disorder (CIA); and

3. To identify clinical and demographic factors that predict better response to an inpatient admission (i.e. greater improvement in the parameters/scores outlined in).

The request has been circulated to the Tara Research Committee meeting and no concerns were raised.

4. Financial implications

No costs will be incurred by either the institution or the individual participants.

5. Recommendations

In view of the above it is recommended that permission is granted for Dr Meddows-Taylor to conduct research at Tara Hospital pending full ethical clearance and obtaining an NHRD number.

Proposer

Appendix D: Change of supervisor forms:

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

FACULTY OF HEALTH SCIENCES

RECOMMENDATION FOR APPOINTMENT OF SUPERVISOR(S) OF RESEARCH REPORT, DISSERTATION OR THESIS

Motivation / Reason for Appointment: _____**Dr. Jones has been involved in scientific research for many years. She has supervised numerous research projects, and has extensive knowledge in the area of Eating Disorders.**

Prof Janse Van Rensburg, has been involved in research for many years, and has supervised similar studies around eating disorders in the past.

Recommendation of Division / Department / School: Co Supervisor absolute necessity as Supervisor is going on Maternity leave, Supervisor will need to complete requirements urgently / imminently

Student Surname and Full name(s)	**JESSICA MEDDOWS-TAYLOR**
Student number	**9803567D**
Degree	**MMED-PSYCH**
Div / Dept / School	**PSYCHIATRY**
Title	**A retrospective review of the efficacy of Tara Hospital's inpatient eating disorders programme in addressing physical, behavioural, psychological, and psychosocial symptoms**

(Supervisor 1): _____**DR MEGAN JONES**_____

Supervision %: **50**_____

Supervisor Qualifications: **MSc Clinical Psychology, PhD**_____

Supervisor Department: ~~PSYCHOLOGY~~ Psychiatry

Supervisor Telephone: **0834427616**_____ E-mail: **meganjones@wits.ac.za**_____

Supervisor 2: _____

): _____Prof Janse Van Rensburg _____

Supervision %: **50**_____

Supervisor Qualifications _____

Supervisor Department: _**Psychiatry**____ - Associate Professor_____

Supervisor Telephone: **0828078103**_____ E-mail: Albert.JanseVanRensburg@wits.ac.za

(Name &Surname)

Supervisor 3:

_____**n/a**_____

(Name &Surname)

Supervisor 1 Signature: _____ **Supervisor 2** Signature: _____ **Supervisor 3** Signature: _____

RECOMMENDATION BY HEAD OF DIVISION / DEPARTMENT / SCHOOL:

Ugasvaree Subramaney _____ 11.2.2020.

(Full name(s) and Surname) (Sign) (Date)

APPROVAL BY CHAIR OF ASSESSOR GROUP:
(On behalf of the FGSC)

_____ _____ _____

(Full name(s) and Surname) (Sign) (Date)

PLEASE NOTE: RECOMMENDATION FOR APPOINTMENT OF SUPERVISOR(S) FOR CIRCULATION TO THE FGSC FOR APPROVAL

APPLICATION FOR CHANGE OF APPROVED SUPERVISOR(S) OF RESEARCH REPORT, DISSERTATION OR THESIS

Please indicate: Additional Supervisor ☐ Withdrawal of Supervisor ☐X

Motivation / Reason for addition / withdrawal of Supervisor: _____Supervisor has passed away

_____

Recommendation of Department / School: __As candidate was in the final stages of MMED, HOD will assist to ensure candidate can complete on time to ensure registration for CMSA examinations. HOS to approve

_____

Student Full name(s) and Surname	Jessica Meddows Taylor		
Student Number	9803567D		
Degree	MMED(Psychiatry)	Department	Psychiatry
Title	A review of the clinical efficacy of an in-patient eating disorders programme		

Current Supervisor (Full name &Surname)	Prof Ugasvaree Subramaney	Supervision %	100
Supervisor Qualifications	MBBCH, FCPSYCH(SA), MMED(PSYCHIATRY), PHD		
Supervisor Department/Address	DEPT OF PSYCHIATRY, AREA 459, CMJAH, JUBILEE ROAD, PARKTOWN		
Supervisor Telephone	011 7172127	E-mail	Ugasvaree.subramaney@wits.ac.za

Withdrawing Supervisor (Full name &Surname)	PROF ALBERT BERNARD JANSE VAN RENSBURG	Supervision %	100
Supervisor Qualifications			
Supervisor Department/Address			
Supervisor Telephone		E-mail	

Additional Supervisor (Full name &Surname)		Supervision %	
Supervisor Qualifications			
Supervisor Department/Address			
Supervisor Telephone		E-mail	

Appendix E: Turn-It IN

Document Viewer

Turnitin Originality Report

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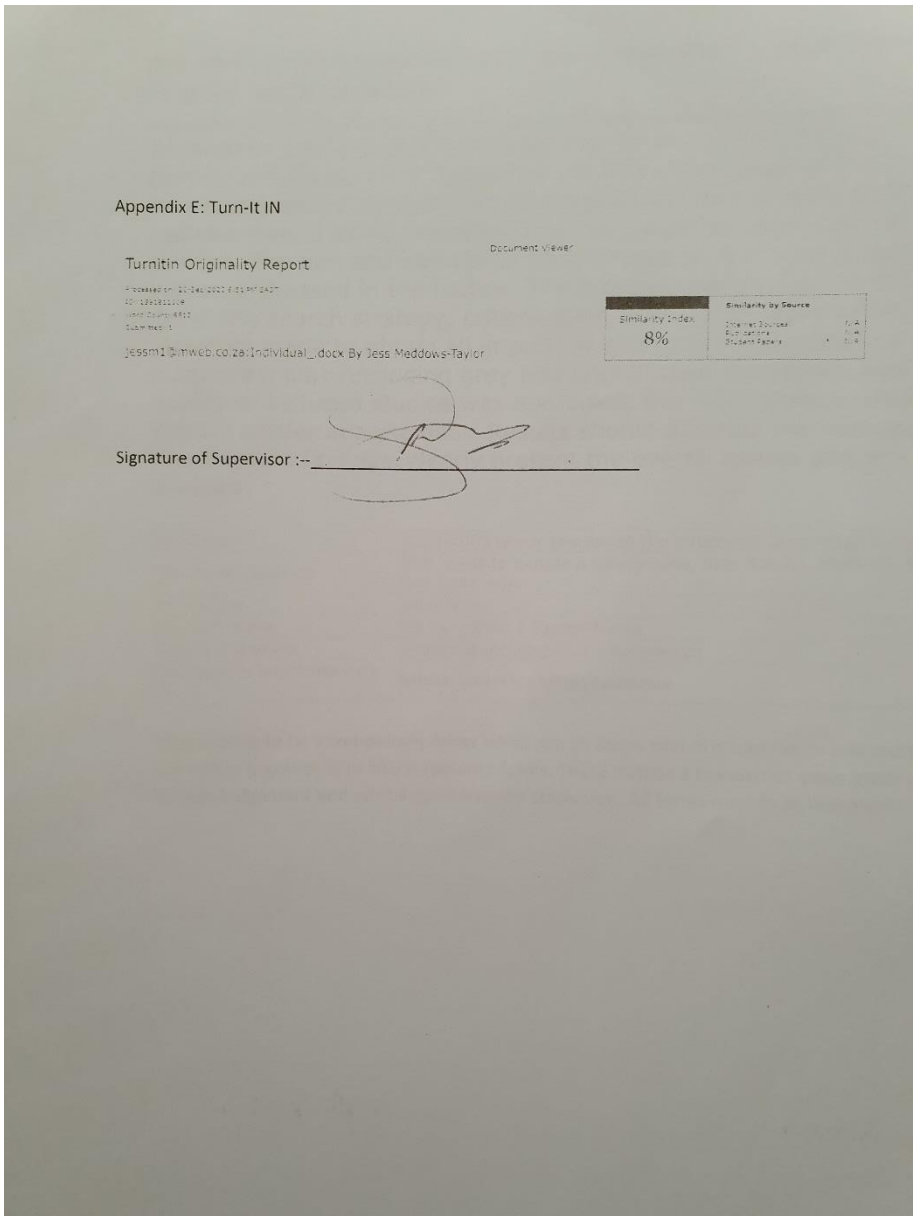

Appendix F: Guidelines for Authors submitting to the South African Journal of Psychiatry.

Original Research Article

An original article provides an overview of innovative research in a particular field within or related to the focus and scope of the journal, presented according to a clear and well-structured format. Systematic reviews should follow the same basic structure as other original research articles. The aim and objectives should focus on a clinical question that will be addressed in the review. The methods section should describe in detail the search strategy, criteria used to select or reject articles, attempts made to obtain all important and relevant studies and deal with publication bias (including grey and unpublished literature), how the quality of included studies was appraised, the methodology used to extract and/or analyse data. Results should describe the homogeneity of the different findings, clearly present the overall results and any meta-analysis.

Word limit	3000-4000 words (excluding the structured abstract and references)
Structured abstract	250 words to include a Background, Aim, Setting, Methods, Results and Conclusion
References	60 or less
Tables/Figures	no more than 7 Tables/Figure
Ethical statement	should be included in the manuscript
Compulsory supplementary file	ethical clearance letter/certificate

There needs to be a **compulsory cover letter** which forms part of a submission and must be submitted together with all the required forms. These include a manuscript cover letter and an acknowledgement and ethical consideration statement. All forms need to be completed in English.