EXAMINING THE ASSOCIATIONS BETWEEN SLEEP BEHAVIOURS, EMOTIONAL REGULATION AND DISTRESS

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By

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Declaration

I confirm that the research presented in this thesis is my own, original work. It has been written and submitted in part fulfilment of the degree of Doctorate in Clinical Psychology. It has not, in whole or in part, been submitted for any other academic award. I have fully acknowledged and referenced all sources included in this thesis. I confirm that this work was checked for completeness prior to submission.

Examining the associations between sleep behaviours, emotional regulation and distress

Sarah Elizabeth May Henderson

Thesis abstract

Difficulties with maintaining optimal sleep behaviours are widespread. Evidence suggests significant relationships between sleep disturbances and health outcomes, with consequences including increased risk, severity, and difficulties with management of health conditions. Disrupted sleep behaviours are associated with inefficient self-regulation and emotional regulation suggesting sleep behaviours as a modifiable risk factor for inclusion in psychological interventions for health management.

Systematic literature review

Social jetlag (SJL), a misalignment between mid-point of sleep on work and free days, has been suggested as a factor in mental health. Biological and social changes characteristic of young people may increase propensity for SJL and distress. The narrative review included seven quantitative papers to assess the relationship between SJL and mental health in young people. Although evidence was equivocal, associations between depression and SJL in female participants particularly in high latitude regions were indicated. An agreed outcome set for mental health and sleep research should be developed to support further research into these relationships.

Research project

Diabetes-related distress (DRD) is associated with poor emotional regulation and poor diabetes outcomes, whilst optimal sleep behaviours and self-compassion have been linked with improved emotional regulation and health outcomes. This cross-sectional study assessed relationships between sleep behaviours, self-compassion, and DRD in a sample of people with type 2 diabetes mellitus (n=136). Statistical analysis identified significant associations between sleep behaviours, DRD, and self-compassion. Daytime sleepiness, SJL, age, total self-compassion, and negative subscales of self-compassion were unique predictors of DRD, with daytime sleepiness partially mediating the relationship between self-compassion and DRD. Psychological work to reduce DRD should focus on reducing negative traits of self-compassion and include consideration of sleep behaviours. Further research is needed to establish causality and long-term impact, as well as to develop clinical resources to support the effective management of the psychological impact of DRD.

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Thesis abstract	297
Systematic literature review	7017 (excluding tabulated data, figures, and reference list)
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Mandatory appendices (indicated with *)	3142
Non-mandatory appendices	4032
Total thesis word count	19676 (excluding mandatory appendices, tabulated data, figures, and reference lists)

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List of abbreviations

AXIS	Appraisal tool of cross-sectional studies
BDI	Beck Depression Scale
CES-D	The Center for Epidemiological Studies – Depression scale
CODEC	Chronotype of Patients with Type 2 Diabetes and Effect on Glycaemic Control study
DASS-21	Depression, Anxiety and Stress Scale
DDS	Diabetes Distress Scale
DRD	Diabetes-related distress
ESS	Epworth Sleepiness Scale
GSS	Global Seasonality score
HbA_{1c}	Glycated haemoglobin
MCTQ	Munich Chronotype Questionnaire
MDQ	Mood Disorder Questionnaire
MSF	Mid-point sleep on Free Days
MSW	Mid-point sleep on Work Days
NHS	National Health Service
OSA	Obstructive Sleep Apnoea
SCS	Self-compassion Scale
SD	Standard deviation
SJL	Social jetlag
SPAQ	Seasonal Pattern Assessment Questionnaire
SPEQ	Specific Psychotic Experiences Questionnaire
STAI	State-trait anxiety inventory
T2DM	Type 2 diabetes mellitus
TSD	Total sleep duration
WdSD	Weekday sleep duration
WeSD	Weekend sleep duration

Part one: Systematic literature review

ASSOCIATIONS BETWEEN SOCIAL JETLAG AND MENTAL HEALTH IN YOUNG PEOPLE: A SYSTEMATIC REVIEW

Target Journal: Chronobiology International (Submitted)

See Appendix C for author guidelines

Presented here using BPS Style guidelines

1. Abstract

Background: Adolescence and early adulthood is a transitional period associated with a number of key physiological, social and psychological changes. Sleep difficulties, notable in this age group, may adversely affect physical and mental health. Of interest is the impact of the natural shift towards a more evening-type sleep pattern (chronotype) seen in young people, whilst social constraints encourage early waking to fit with school/work timings. This leads to a misalignment in sleep timing between week days and weekends, known as social jetlag, which may contribute to emerging mental health difficulties seen during this age group. A systematic literature review was undertaken to investigate the association between social jetlag and mental health outcomes.

Method: Systematic searching of electronic databases (The Cochrane Library; PsycINFO; CINAHL; Scopus; and PubMed), grey literature and review of reference lists identified seven studies which assessed associations between social jetlag and mental health outcomes in young people. A quality appraisal was completed using the Appraisal Tool for Cross-Sectional Studies. A narrative review was undertaken.

Results: Findings appeared equivocal; however significant associations were seen between social jetlag and clinical depression and seasonal depression, in female participants and high latitude regions. Quality of included studies was moderate (10–13 criteria met).

Discussion/conclusion: The ambiguous results found may result from confounding factors, particularly non-comparable methods of measuring social jetlag and mental health both in this age group and the selected studies. Future research should address the lack of homogeneity through the development of an interdisciplinary core outcome set, and agreement on a standardised measure and calculation for social jetlag.

2. Introduction

2.1. The age of "young people"

Adolescence and early adulthood is a transitional point between childhood and adulthood characterised by moral exploration, psychological changes (including social role and identity formation), as well as physical and biological changes (Sawyer et al., 2018; Steinberg & Morris, 2001). Increasing consensus indicates that development of young people[1] is culturally and societally constructed, and environmentally, genetically and biologically driven, leading to slower or faster development across populations (Twenge & Park, 2017). Thus the timing and duration of this period of development may be fluid: contingent on time and place (Patel et al., 2007; Sawyer et al., 2018). Recent research suggests use of a broader age range in health research, to include all "young people" (10–24 years old), and to address changing needs and variations in this group across populations and cultures (Sawyer et al., 2012; Sawyer et al., 2018).

2.2. Mental health and young people

Whilst adolescence and early adulthood is a critical period of change and transition, it also intimates a time when many mental health difficulties begin (Patel et al., 2007). Mental health difficulties burgeon in this group, particularly amongst girls and young women (Gunnell et al., 2018) with prevalence rates between 8 and 57% dependent on setting (Patel et al., 2007). Given the developmental, behavioural and psychological changes seen, understanding risk factors and potential mediators of mental health in young people may help to mitigate potential distress.

2.3. Sleep and young people

Of potential factors affecting mental health in young people, changing sleep patterns are receiving increasing attention. Sleep arises from a complex interaction between social and environmental cues (exogenous) as well as

[1] A range of terms are used to describe people in this age group. The World Health Organisation defines "adolescence" between the ages of 10-19 years old; whilst the United Nations refers to "youth" as being aged 15-24. Both organisations use "young people" (10-24 years old) to describe the combination of these age groups, where a reliance on parents continues alongside a shift towards independence (World Health Organisation, 1999). This will be the definition used throughout.

internal (endogenous) factors including multiple neural networks, hormones and neurotransmitters (Foster et al., 2013). Internally two complementary but distinct circadian systems influence wakefulness and sleep (Borbély, 1982; Borbély et al., 2016): “sleep pressure” and “the circadian pacemaker” (also known as the biological clock). Sleep is an essential biological function that activates endogenous maintenance processes, such as cell division, growth and metabolism (Hagenauer & Lee, 2012). Under free-running conditions, circadian systems drive a daily propensity to sleep, closely approximating the 24-hour solar clock but with individual variability: this individual preference for sleep/wake timings is known as a chronotype, with preferences for early morning (“Larks”) or late evening (“Owls”) based on the optimal pattern of these circadian rhythms (Roenneberg et al., 2003). Differences in sleep timing preferences are underpinned by genetics and age and entrained by environmental and social cues (zeitgebers), such as social timing, light exposure, or dietary routines (Randler, 2016; Roenneberg et al., 2003).

Adequate sleep in line with individual circadian preference is an important element of normal growth and development in young people (Bruce et al., 2017; Crowley et al., 2007), however sleep disturbance amongst young people is common (Chandrakar, 2017). This may reflect a shift towards a more evening chronotype (Hagenauer & Lee, 2012) which reaches maximum lateness between 16–21 years before shifting back towards a more morning chronotype (Randler et al., 2019; Roenneberg et al., 2004; Tonetti et al., 2008). This shift is driven by hormonal changes causing alterations to the endogenous rhythm period and an individual’s sensitivity to cues of entrainment (Hagenauer & Lee, 2012). Alongside this natural internal circadian shift, sleep disruption may also be linked to increased use of electronic equipment, such as television, computer games and mobile phones, introducing light disturbance and delaying onset and duration of sleep (Cain & Gradisar, 2010; Touitou, 2013). Sleep duration significantly shortens from the onset of adolescence, mainly on school/work days, with substantial sleep loss evident in those with more evening chronotypes (Foster et al., 2013). Early rise times to align with school start times (Wheaton et al., 2016) and delayed sleep onset due to after-school study requirements and extra-curricular and social activities, alongside a changing

homeostatic drive to sleep later, are likely further contributors to a “perfect storm” resulting in significant limiting of sleep duration and quality with potentially negative consequences (Carskadon, 2011).

2.4. Social jetlag

One recently described sleep characteristic associated with physical, behavioural, and mental health risk is social jetlag (Beauvalet et al., 2017). Social jetlag (SJL) encompasses the misalignment between an individual’s chronotype and the social requirements of activities, such as work or school (Wittmann et al., 2006). It is measured as the absolute difference between mid-point of sleep on work days (MSW) and mid-point of sleep on free days (MSF), with mid-point of sleep being calculated as the time halfway between onset and offset of sleep. Prevalence of SJL exceeding one hour was reported as between 24–69% of the population (Koopman et al., 2017; Mota et al., 2017; Roenneberg et al., 2012; Rutters et al., 2014) and argued to reflect increasing industrialisation that drives a need to adjust sleep timings to fit the socially-fixed zeitgeber of school/work start time (Chandrakar, 2017). Increased SJL and chronic sleep loss is particularly seen in individuals with more evening chronotype as the standard patterns of early school/work start times increase misalignment with the biological drivers of the sleep-wake cycle (Roenneberg et al., 2012).

The association between SJL and health and behavioural outcomes is increasingly being studied (Beauvalet et al., 2017): evidencing correlations with a range of health risks, such as obesity (Mota et al., 2017; Roenneberg et al., 2012), metabolic disorders (Parsons et al., 2015; Wong et al., 2015), substance misuse (Wittmann et al., 2010), and depressive symptomology (Levandovski et al., 2011). A recent review of SJL research across different populations and the lifespan (Beauvalet et al., 2017) concluded an unclear role of SJL, with some studies observing significant associations between SJL and health outcomes, whilst many did not. The causal links between SJL and health behaviours are yet to be established: SJL may lead to or influences health and behavioural outcomes; however circadian disruption, such as SJL, may be impacted by health behaviours, such as substance use, alcohol, or exercise (Adan et al.,

2012). Diversity across study samples and methodologies is problematic in reviewing and comparing SJL and health outcome research (Beauvalet et al., 2017).

Given the potential for high levels of SJL in young people it may have implications for their mental health risk. Identification of such risks could offer health and education professionals a novel, modifiable lifestyle risk factor to incorporate into identification, prevention and management for young people experiencing distress.

2.5. Rationale for current review

Scrutiny of the impact of SJL indicates its role in relation to mental health as well as cardiometabolic and behavioural outcomes. Given requirements to adhere to socially-prescribed school/work start times, in concert with a shift towards a more evening chronotype, young people may be more vulnerable to SJL (Touitou, 2013) and this may contribute to distress and mental illness. Despite interest in the mental health impact of SJL in young people, to our knowledge no systematic review has been identified focusing on this age group.

2.6. Objectives

This review undertook a rigorous search strategy to identify research measuring SJL and mental health in young people with the objective of assessing the relationship between SJL and mental health outcomes in young people. Due to heterogeneity between study characteristics and methodologies (Table 1) it was not possible to pool studies to carry out a meta-analysis to explore the relationship between outcome measures further, therefore a narrative review is presented.

3. Method

3.1. Study Design

A protocol was developed to define the systematic review objectives, inclusion and exclusion criteria, search strategy and data extraction methods. The systematic review was based on Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines (Moher et al., 2009, Appendix D).

3.2. Search procedure

A systematic literature search was conducted in September 2018 using the following databases: The Cochrane Library; PsycINFO; CINAHL; Scopus (inclusive of Medline and Embase); and PubMed. These databases were chosen to enable a comprehensive search of research related to psychology, health and medicine. Grey literature resources were also reviewed using the following electronic databases: OpenGrey Database; the New York Academy of Medicine Grey Literature Report; British Library EThOS service, and ProQuest Dissertations and Theses. All dates up to 30th September 2018 were included.

Search terms relating to the three areas of interest for this review – SJL, mental health, and young people – were generated and used in the literature search (Appendix E). As SJL is a relatively new concept, search terms were kept broad to ensure that all incidences were included, even where not named (Beauvalet et al., 2017); therefore, a range of search terms relating to sleep characteristics were used.

Reference lists of the identified and eligible articles and relevant review articles were examined to ensure that all relevant articles were included.

3.3. Selection criteria of studies

Articles were screened at two stages: an initial screening of article title and abstract, followed by remaining articles being assessed for eligibility through full-text reading. Articles included met the following inclusion criteria: 1) human participants; 2) English language; 3) age 10–24 years or reported mean fell within this age range; 3) a reported measure of SJL; 4) a measure of mental health reported in relation to SJL; 5) peer-reviewed original empirical studies.

Articles were excluded on the following criteria: 1) review articles, meta-analyses, clinical trials, and qualitative studies; 2) studies where sleep characteristics were the only outcome measure; 3) studies where only behavioural, cognitive or performance-related outcome measures were assessed in relation to sleep characteristics; 4) cohorts with existing sleep-related health conditions (such as insomnia). Although insomnia could be classified as a mental health condition, it was decided to exclude measures of insomnia due to the potential overlap both with mental health outcomes (such as depression and mood conditions) and with accurate measurement of SJL. Figure 1 presents a flow chart displaying the screening procedure.

3.4. Data extraction

A data extraction tool was developed (Appendix F) to record: study characteristics, participant characteristics, study design and methodology, outcome measures, relevant data/statistical analysis, and conclusions. In line with chronobiological research guidance (Portaluppi et al., 2010), geographical location, season, and setting of research were also recorded where possible. Two reviewers independently reviewed the selected studies using the data extraction tool, and compared for consistency. Discrepancies were resolved through discussion between the two reviewers.

3.5. Quality assessment

Following the selection of final studies, a quality assessment tool was chosen to assess and describe the quality of the selected studies, rather than as an exclusion strategy. A limited number of quality assessment tools are available for cross-sectional studies (Sanderson et al., 2007; Zeng et al., 2015). Several appraisal tools have been used to assess quality of cross-sectional studies (e.g. ROBINS-I, STROBE, CASP); however, the suitability and validity of these tools for this purpose has been questioned particularly in relation to the lack of specificity, generalisability and transferability (Downes et al., 2016). Following examination of potential tools, the Appraisal Tool for Cross-Sectional Studies (AXIS; Downes et al., 2016) was selected to assess the quality of studies included in this review.

AXIS is a twenty-question critical appraisal tool designed for use with cross-sectional studies (Appendix G). AXIS was designed to address the lack of specialised assessment tools for cross-sectional studies; utilising “Delphi methodology” and recognised reporting guidelines to develop a robust and specialised tool (Downes et al., 2016). AXIS offers a comprehensive and relevant tool covering three main areas of interest (Kiss et al., 2018): design quality (seven questions), reporting quality (seven questions), and introduction of bias (six questions). The questions were answered with “yes”, “no” or “do not know”. AXIS does not have a specified summary score of overall quality (Downes et al., 2016) due to concern regarding the variability and inconsistency of summary scores across scales (Greenland & O'Rourke, 2001; Juni et al., 1999; Sanderson et al., 2007). In this review, in line with other studies using AXIS (Kiss et al., 2018; Wong et al., 2018), each criterion was assessed separately as being met (a “yes” response) or not being met (a “no” or “do not know” response)[2]. Quality was assessed on how many of the individual criteria were met (total=20), with 16 or over being considered a high-quality study.

[2] Exceptions to this were questions 13 and 19, where reverse scoring was used (Wong et al. 2018).

4. Results

4.1. Literature search

1285 articles were identified (Figure 1) and imported into Endnote reference management software. Duplicates were removed using an Endnote function and remaining duplicates were removed manually. Article title and abstracts for the remaining 884 articles were assessed and 154 articles selected for full-text review. At this stage the majority of articles were excluded due to having no measure of mental health or SJL, or falling outside of the age criteria. Following full-text review, seven papers were selected for inclusion in the review (Table 1).

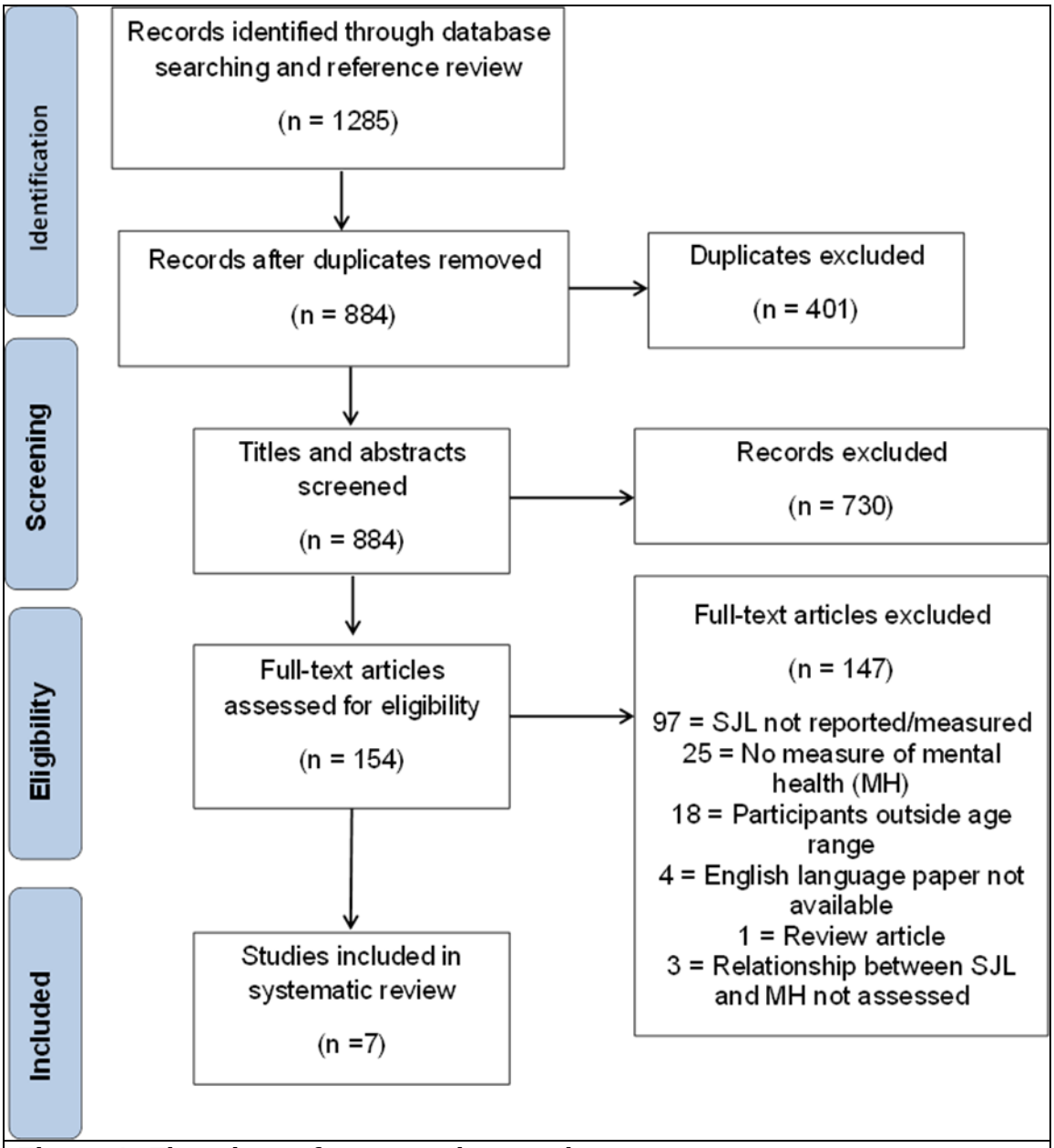

Figure 1: Flowchart of systematic search process

4.2. Selected studies characteristics

The seven selected studies assessed the relationship between a range of sleep characteristics and mental health measures in young people, aged 10–24 years. 9626 participants were included across the seven studies, with 55.58%[3] identifying as female. The studies evaluated the relationship between SJL and depression, seasonal depression, anxiety, psychosis-like symptoms, mania, and overall mental health risk. Some studies reported on a single mental health outcome whereas others reported multiple outcomes (Table 1 and 4). Studies were situated in a range of countries, with the majority within Europe.

All studies measured SJL via self-report measures: five (Borisenkov et al., 2015; de Souza & Hidalgo, 2014; Keller et al., 2017; Polugrudov et al., 2016; Sheaves et al., 2016) used the Munich Chronotype Questionnaire (MCTQ); whilst Díaz-Morales (2015) and Mathew et al. (2018) utilised bespoke questionnaires regarding sleep characteristics. Polugrudov et al. (2016) collected sleep diary data, whilst Keller et al. (2017) collected actigraphy measurements. Neither reported using these to calculate SJL, although Keller and colleagues reported a high correlation between chronotype calculated via the MCTQ and via actigraphy which may indicate equal reliability of self-report and objective measures. High levels of SJL were seen in participants across all studies with considerable variation across the sample populations, with mean ranging from one hour to three hours (Table 2). Two studies (de Souza & Hidalgo, 2014; Polugrudov et al., 2016) reported negative SJL.

The majority of studies sampled from non-clinical populations, with only one study (Keller et al., 2017) including participants who had a previous diagnosis, but no longer symptoms, of “unipolar depression”.

A summary of study characteristics is presented in Table 1 and a summary of statistical outcomes is presented in Table 4.

[3] Figure excludes Mathew et al 2018 data as not reported.

Table 1: Selected studies characteristics

Author and year	Study design	Sample size	Age (mean)	Sex (Female)	SJL (measure; calculation)	Mental Health	Mental Health Measure	Location	Season	Significance between key variables	QA score (max 20)
Borisenkov et al., 2015	Cross-sectional	3435; 2614 (analysed)	14.8 ± 2.6 (Range: 10-20)	55.8%	MCTQ; MSF – MSW	Seasonal Depression	SPAQ	Northern European Russia	Autumn – Spring	Yes	12
De Souza & Hidalgo 2014	Cross-sectional	351	14.7 ± 1.86 (Range: 12-21)	70.4%	MCTQ; Difference between MSF and MSW	Depression	BDI (Brazilian Portuguese)	Southern Brazil	Unknown	No	11
Díaz-Morales 2015	Cross-sectional	1406	13.95 ± 1.69 (Range:12-16)	50.9%	Self-report questionnaire; |MSF – MSW| (midpoint between bedtime and rise time)	Trait Anxiety	STAI-T	Spain	Unknown	No	11
Keller et al. 2017	Cross-sectional	19 patients 19 healthy	16.51 ± 1.68 16.06 ± 1.68 (Range: 12-19)	68% 63%	MCTQ; Absolute difference between MSW and MSF	Depression	BDI-II (German)	Germany	Summer	No	13
Mathew et al., 2018	Cross-sectional	2931	15	Unknown	Self-report questionnaire; |MSF – MSW| (weekend – school night)	Depression	CES-D	USA	Year Round	Yes	10
Polugrudov et al., 2016	Cross-sectional	62	22 ± 2	56.5%	MCTQ; MSF – MSW	Seasonal Mood; Depression; State-Trait Anxiety	SPAQ; BDI; STAI	Northern European Russia	Winter – Spring	Yes	12
Sheaves et al., 2016	Cross-sectional	1403	*Median:* 21 (IQR: 20-23)	55.6%	MCTQ; MSF – MSW	Psychosis; Mania; Depression; Anxiety	SPEQ; MDQ; DASS-21; DASS-21	UK	Spring	No	11

Abbreviations: MCTQ (Munich Chronotype Questionnaire); MSF (mid-point sleep on free days); MSW (mid- point sleep on work days); SPAQ (Seasonal Pattern Assessment Questionnaire); STAI-T/STAI (State-Trait Anxiety Inventory); BDI (Beck-Depression Inventory); CES-D (Center for Epidemiologic Studies Depression Scale); SPEQ (Specific Psychotic Experiences Questionnaire), MDQ (Mood Disorder Questionnaire); DASS-21 (Depression, Anxiety, and Stress Scales – short form).

Table 2: Mean and range of social jetlag in study populations		
Author and year	**Mean social jetlag (minutes)**	**Range of social jetlag (hours)**
Borisenkov et al., 2015	151.66 ± 87.62 *	Not reported
De Souza & Hidalgo 2014	104.83 ± 83.69 *	Not reported
Díaz-Morales 2015	146 ± 67	Not reported
Keller et al. 2017	149 ± 49.16 *	Not reported
Mathew et al., 2018	Not reported	Not reported
Polugrudov et al., 2016	65% participants reported social jetlag > 60 minutes	-0.5 – 3.5
Sheaves et al., 2016	73 (median)	0.38 – 2
* calculated from data reported in paper		

4.3. Methodological quality of included studies

The quality of included studies ranged from 10 to 13 criteria met: Table 3 provides a summary of the quality appraisal of the selected studies.

Criteria related to quality of reporting were the highest met (range: 4–7; mean: 5.7). All studies provided a clear statement of the research aims and objectives, and reporting of methodology, measures used and basic data were largely described across studies. However, the population of interest (reference population) was not clearly defined in three studies making the focus of the research unclear.

Criteria relating to study design were less well met (range: 2–5; mean: 3.9). The cross-sectional design was appropriate for the aims in all studies and outcome variables were largely appropriate to these aims. However, no study justified sample size or reported on power analysis, and descriptions of the procedure for sampling were limited. Ethical approval was gained for all studies selected.

Questions relating to risk of bias were rated poorly (range: 1–4; mean: 2) across the studies. Reporting on the non-responders and recruitment strategies was limited across studies; only Sheaves et al. (2016) considered potential non-respondents or bias in the sample recruited. The representativeness of the sample populations was uncertain due to an unclear reference population, small sampling frame, small sample size, high levels of homogeneity within the sample, or a lack of participant demographics. Discussion of limitations was missed from one study and was only briefly included in three.

Table 3: Quality assessment ratings using Appraisal Tool for Cross-Sectional Studies (AXIS; Downes et al., 2016)

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	**Total** (max 20)
Author and year	*RQ*	*SD*	*SD*	*RQ*	*SD*	*RB*	*RB*	*SD*	*RB*	*RQ*	*RQ*	*RQ*	*RB*	*RB*	*RB*	*RQ*	*SD*	*RQ*	*SD*	*SD*	
Borisenkov et al., 2015	✓	✓	×	✓	–	–	×	✓	–	✓	✓	✓	–	×	×	✓	✓	✓	✓	✓	12
De Souza & Hidalgo, 2014	✓	✓	×	✓	–	–	×	✓	✓	✓	✓	✓	–	×	–	×	–	✓	✓	✓	11
Díaz-Morales, 2015	✓	✓	×	✓	✓	✓	×	–	–	✓	✓	✓	–	×	✓	✓	×	×	–	✓	11
Keller et al., 2017	✓	✓	×	✓	×	✓	×	✓	✓	✓	✓	✓	–	×	×	×	✓	✓	✓	✓	13
Mathew et al., 2018	✓	✓	×	×	–	–	–	✓	–	×	✓	×	✓	–	–	✓	✓	✓	✓	✓	10^
Polugrudov et al., 2016	✓	✓	×	×	×	×	×	✓	✓	✓	✓	✓	✓	×	✓	✓	×	–	✓	✓	12
Sheaves et al., 2016	✓	✓	×	×	×	×	✓	–	✓	✓	✓	×	✓	×	✓	✓	×	✓	×	✓	11

See Appendix F for AXIS questions. ^ Conference abstract.
Question grouping (Kiss et al., 2018): RQ = reporting quality; SD = study design; RB = risk of bias
Ratings: ✓/Green = criteria met; – /Orange = don't know/partially met; ×/Red = criteria not met

4.4. Social jetlag and depression

Six studies evaluated the role of SJL with depression (including seasonal depression) in young people (Table 1) utilising a range of outcome measures.

The Beck Depression Scale (BDI; Beck et al., 1996; Beck et al., 1961) was used by three studies; two used the original BDI, whilst one utilised the revised version (BDI-II). The BDI is a self-report measure to assess severity of depression in a range of settings and populations including young people (Smarr & Keefer, 2011). Two studies used alternative validated outcome measures of depression: Depression, Anxiety and Stress Scale (DASS-21; Lovibond & Lovibond, 1995) and The Center for Epidemiological Studies – Depression scale (CES-D; Radloff, 1977). DASS-21 was designed for use in both clinical and research settings to provide an overview of human distress based on three scales (depression, anxiety and stress/tension) and possesses adequate construct reliability within a non-clinical UK population (Henry & Crawford, 2005) and in adolescent populations (da Silva et al., 2016; Szabo, 2010). The CES-D is a self-report questionnaire designed to best represent depressive symptomology in a general population (Radloff, 1977). Each study used a translated version appropriate for the setting.

de Souza and Hidalgo (2014) sampled from a large epidemiological study of a young Brazilian student population of predominantly European heritage. SJL was calculated as a continuous measure and further reported categorically as <2-hours and ≥2-hours. For depression, BDI scores were also assessed continuously and categorically, with BDI≥10 used as a clinically relevant score (11.7% of sample). Although SJL was one of the factors predicting depression, mid-point of sleep on school nights was a better predictor of depression. No significant association was found between depression, as measured by the BDI, and SJL; nor when grouped by severity of depressive symptoms (BDI<10 compared to BDI≥10).

Keller et al. (2017) utilised BDI-II to assess depression in a small sample of young people already recruited to an existing genetics study. Participants were recruited into two groups: patient group (young people with remittent depression) and control group (young people with no previous psychiatric

diagnoses). Seven participants were receiving antidepressant medication, although the authors reported that no variables differed due to this. SJL was comparable between groups, however BDI was significantly higher in the patient group ($p<.001$). No significant association was seen either within or between groups for SJL and BDI score.

Sheaves et al. (2016) included a measure of depression symptomology (DASS-21) when assessing mental health risk and sleep characteristics in a UK university population. SJL was measured as a continuous measure and was reported across the sample population. Within the sample 7.4% (n=104) were receiving mental health treatment and 16.6% (n=233) reported a mental health diagnosis. No significant correlation was evident between SJL and depression symptomology.

In contrast four studies found significant associations between SJL and measures of depression. Polugrudov and colleagues (2016) identified a statistically significantly incident of depression in a small sample of "young [mean age 22] inhabitants of high latitude" Russians when comparing SJL by categories: SJL (≥1-hour) compared to non-SJL (<1-hour). This association was seen regardless of gender.

Mathew and colleagues (2018) identified a significant association between measures of SJL and depression in young people who took part in Wave 6 (15th year) of the Fragile Families and Child Wellbeing Study (FFCWS), a cohort study of families of children born between 1998 and 2000 across cities in the USA (Reichman et al., 2001). A modified (five item) version of the CES-D was utilised as previous research (Perreira et al., 2005) suggested this as a more valid measure in a multi-ethnic population. Greater levels of SJL were associated with higher rating of depressive symptoms in female, but not male, participants.

Two studies focussed specifically on evaluating SJL in seasonal depression using the Seasonal Pattern Assessment Questionnaire (SPAQ; Rosenthal et al., 1987), a research and screening tool of Seasonal Affective Disorder (SAD) characteristics (Mersch et al., 2004). Polugrudov et al. (2016) assessed seasonal depression using the SPAQ. Although no statistically significant

relationship was seen between seasonal depression severity and SJL across the sample population, the authors identified that Global Seasonality Score (GSS; the sum of self-rating of an individual's seasonal variation across five domains) showed "a tendency to increase" in the ≥1-hour SJL group. A statistically significant difference was seen between women in the SJL group compared to women in the non-SJL (<1-hour) group for GSS score.

Borisenkov et al. (2015) investigated seasonal depression in a younger (mean: 14.8 ± 2.6 years) sample population also from high latitude areas of Russia. SJL was reported continuously by gender. Utilising three questions from the SPAQ (including GSS), participants were assigned to groups based on severity (none, sub-clinical, clinical) and type of seasonal depression (winter, summer, both). As prevalence of summer depression was described as "very low" (2.6%) in the sample population, this data was not further analysed. A significant difference in the level of SJL was seen for female participants, but not for male participants, across severity categories - with those with greater winter depression severity having a higher level of SJL.

4.5. Social jetlag and anxiety

Three studies evaluated the relationship between SJL and anxiety in young people. Two studies evaluated anxiety using the State-Trait Anxiety Inventory (STAI; Spielberger et al., 1983), a 40-item measure which contains scales for trait (20-items) and state (20-items) anxiety, whilst one study evaluated clinical anxiety via the DASS-21 (Lovibond & Lovibond, 1995).

Polugrudov et al. (2016) assessed levels of state-trait anxiety using the STAI. No significant difference was reported between severity of trait-anxiety for those with SJL (≥1-hour) compared to a non-SJL (<1-hour) group.

Díaz-Morales (2015) also found no association between trait-anxiety (assessed via STAI), with younger high school students from middle-income families; although, a significantly higher rate of SJL was identified in female participants.

Sheaves et al. (2016) also found no significant correlation between SJL and clinical anxiety symptoms (utilised the DASS-21).

4.6. Social jetlag, psychosis and mania

Sheaves and colleagues (2016) assessed paranoia and hallucinatory experiences utilising scales from the Specific Psychotic Experiences Questionnaire (SPEQ; Ronald et al., 2014); and mania via the Mood Disorder Questionnaire (Hirschfeld et al., 2003). No statistically significant correlation was seen between SJL and hallucinations, paranoia or mania. A composite risk score was created by normalising the five mental health characteristics scores (paranoia, hallucinations, mania, depression, and anxiety) to a linear scale (0–1) and used hierarchical clustering to obtain three risk groups: high, medium and low. MSF indicated a circadian phase delay in the medium- and high-risk groups, compared to the low-risk group; however no statistically significant differences were seen between the risk groups and levels of SJL, with both the lowest and highest reported SJL falling in the high risk group.

Table 4: Statistical outcomes for selected studies by mental health condition assessed				
Author and year	**Mental Health outcome measure**	**Social jetlag (SJL) and Mental Health outcome results**	**Relationship between SJL and Mental Health outcome**	**Other Conclusions**
a) *Depression*				
Borisenkov et al., 2015	SPAQ	SJL continuous Significant difference in level of SJL for female participants between No SAD and subSAD, and No SAD and SAD: Female: Fisher=3.1, p=.04, η2=0.003; Male: Fisher=0.6, p= .57, η2(effect)=0.001	**Significant association between SJL and depression (female only).**	SAD symptoms had a stronger influence on sleep characteristics on school days than on weekends
De Souza & Hidalgo 2014	BDI	SJL continuous and categorised (SJL <2hrs; SJL ≥2hrs). BDI continuous and categorised (BDI <10; BDI ≥10). No significant association between SJL and BDI (r=0.07; p=.19). No significant difference within BDI groups for continuous SJL (t=-0.68, p=.50) or categorical SJL (χ^2 = 1, p=.32). SJL significantly predicted BDI ≥10 (β=.248, p≤.05) until midpoint school days added to hierarchical model. No significant correlation between sexes for BDI and SJL (Male: r=0.136, p=.17; Female: r=0.04, p =.50).	SJL not associated with depression.	Midpoint sleep school days better indicator of depression in study than SJL or midpoint sleep on free days.
Keller et al. 2017	BDI	SJL and BDI continuous. No significant difference between groups for SJL: t(36) = 0.77, p=.45 SJL not significantly associated with depressive symptoms measured by BDI in either group: Patient: r=-0.06, p=.82; Controls: r=0.35, p=.14	SJL not associated with depression.	Weekday sleep earlier and shorter. Chronotype (MSFsc) correlated with BDI in control group only (later chronotype => more depressive symptoms)
Mathew et al., 2018	CES-D	SJL and BDI continuous. Sex moderated the association between SJL and depressive symptoms in females (β=0.10, p<.001) but not males (p=.64).	**Significant association between SJL and depression (female only).**	
Polugrudov et al., 2016	BDI SPAQ	SJL categorised: Non-SJL (<1hr, n=22) and SJL (≥1hr, n=40). BDI higher in SJL group (H=4.84, p<.05). No gender difference seen. Non-significant difference between Global Seasonality Score (GSS) between groups. GSS showed "a tendency to increase in SJL group". Women with SJL had a significantly higher GSS compared to women without (β=0.51, CI: 0.21–0.81; F=10.9, p<.002; η2=0.24).	**Significant association between SJL and seasonal depression (female only) and depression.**	In non-SJL group, wrist temp significantly higher at night and lower during day compared to SJL group Slight difference in sleep patterns (SJL slight phase delay of sleep-wake rhythm). Tendency for increased Cortisol awakening response in SJL group. Large variance within group.

Sheaves et al., 2016	DASS-21	SJL and DASS-21 continuous. No significant correlation between SJL and depression: ρ=0.02	SJL not associated with depression	Chronotype: significance between groups p=0.012; high risk had "descriptively later MSFsc than medium" but not significant (z=0.97, p=.33). Medium >low MSFsc (z=-2.67, p=.008). Significant difference between risk groups for measures of insomnia and nightmares
b) *Anxiety*				
Díaz-Morales 2015	STAI-T	SJL continuous. Significant difference seen between sexes for SJL. STAI continuous. Mean: 33.92±7.59 (range: 20-60). No significant correlation found between anxiety and SJL (r=0.03, p≥.05). No significant interaction between gender and anxiety.	SJL not associated with anxiety	Anxiety significantly correlated with age, chronotype, rise times on weekdays and time in bed on weekends. High anxiety: Earlier mean rise time (weekdays) Females: Earlier rise time and bedtime (weekdays); later rise time and greater time in bed (weekend), weekend and higher SJL.
Sheaves et al., 2016	DASS-21	SJL continuous and DASS-21 continuous. No significant correlation between SJL and anxiety: ρ=-0.03	SJL not associated with anxiety	See above
Polugrudov et al., 2016	STAI	SJL categories: Non-SJL (<1hr) and SJL (≥1hr). No significant difference between groups. However, 45% of SJL (compared to 27.3% non-SJL) reported highest anxiety ratings (>46). Clinical cut off lay within "moderate" category.	SJL not associated with anxiety.	See above.
c) *Other*				
Sheaves et al., 2016	SPEQ (Psychosis–like symptoms); MDQ (Mania); Composite Score (Mental Health Risk)	SJL continuous No significant correlation between SJL and Hallucinations (ρ=0.07); Paranoia (ρ=-0.01) and (hypo)mania (ρ=0.01). Composite score created by standardising score from five mental health measures to cluster participants into high, medium or low risk. SJL seen across all categories. No significant difference between clusters ($\chi 2$=8.83, p=.91), however "evidence of a circadian phase delay in high- and medium-risk groups".	SJL not associated with mania or psychosis symptoms	See above

5. Discussion

This systematic review assessed systematically elicited published research regarding SJL and mental health variables in young people, revealing equivocal findings. Significant relationships were seen only between depression and SJL (although not consistently). Significant associations were found only in female participants, except in BDI-measured depression in Polugrudov et al. (2016). Depression was overly represented in the review with six of the seven studies including measures of depression.

SJL is a new phenomenon and although increasingly part of sleep research, exploration of its role and impact on mental health is in its infancy. In this systematic review, the selection process identified that SJL is more often a secondary outcome measure in empirical research. Whilst many studies identified during the initial search stages included measurements such as sleep onset, rise time, or MSW and MSF, SJL was less commonly reported. In continuity with Beauvalet et al. (2017), many studies mentioned SJL as a feature of chronobiology, circadian rhythms, and mental health; however, few measured it as a research variable. Therefore only a small number of studies could be included in the current review.

Given the global prevalence of SJL and mental illness, the reviewed studies offer a limited insight with focus predominantly on a European population and limited ability to generalise to a wider population. Overall, the sample population is small, with no study justifying the sample sizes or providing post hoc power calculations making it difficult to draw conclusions about risk of type I or type II errors.

Of the three studies identifying significant associations between SJL and depression symptomology, two (Borisenkov et al., 2015; Polugrudov et al., 2016) were undertaken in high latitude settings in Russia with high levels of depressive symptoms evident in the sample population, and in the general population (Goodman et al., 2005); whilst the third was undertaken across the USA at differing latitudes. All three studies collected data during spring and winter months; this would include periods of reduced light exposure and seasonal clock changes compared to those undertaken during only summer

months, potentially affecting measures of SJL and depression. Previous research suggests that season of assessment may influence mid-point reporting (Allebrandt et al., 2014; Johnsen et al., 2013), including a shift towards a more morning-type chronotype during summer. Overall, there was limited reporting of biological and social factors relating to sleep, such as light exposure, season, ethnicity, and start-time of school/university/work. Failure to consider these potentially confounding effects on SJL and the complexity of measuring SJL may contribute to the equivocal findings.

Most of the studies reviewed here followed the convention suggested by Wittmann and colleagues for calculating SJL. However, Díaz-Morales (2015) calculated the mid-point of sleep, used to calculate SJL, as the difference between bedtime and rise time (rather than sleep onset and waking) on weekends and schooldays; and the presence of negative SJL reported by de Souza & Hidalgo (2014) and Polugrudov et al. (2016) suggests that the absolute calculation was not utilised in these studies. Ambiguity existed across studies regarding whether mid-points were collected on weekday/weekend or work/free days. These subtle differences in mid-point calculation may provide a different outcome, particularly when relying on self-reports, and where parental rules may dictate bedtimes but not sleep onset, adding to heterogeneity in study methodologies. Revision of the calculation of SJL has been suggested as the current calculation arguably overlaps with measures of sleep deprivation (Jankowski, 2017). Depending on an individual's sleep profile and how competing biological and societal zeitgebers are managed, SJL may have different drivers – unaccounted for by the Wittmann calculation. This is evidenced by the occurrence of negative SJL which, although reported in some studies due to the use of a non-absolute calculation of SJL, was not adequately accounted for in the interpretation of the association between SJL and mental health outcomes. Rather than a linear relationship, negative SJL may affect individuals as positive SJL does, as a result of a mismatch between circadian and social patterns on free days compared to school/work days (for example, a greater social pressure to stay up later on free days to participate in social gatherings). Alternatively it may reveal the social pressures on young people at

weekends, as well as weekdays, overlooking the potential for “free days” to include part-time employment or participation in social activities.

Chronotype shifts over the course of development, with women reaching maximum eveningness around age 19.5 and men continuing to shift until approximately age 21 (Roenneberg et al., 2007), at which point SJL will be at its greatest. SJL may have a cumulative effect on young people with its relative impact only becoming notable in adulthood; alternatively it may be that younger people are “protected” against the effects compared to older counterparts. Thus the associations between SJL and mental health in young people may only be seen when extreme levels of SJL are present or persistent which may account for the equivocal results seen.

There are difficulties in assessing sleep and mental health due to potential overlaps, notably sleep difficulties as part of diagnostic criteria, and as potential exacerbator of some mental health conditions. Sheaves et al. (2016) identified that insomnia and nightmares were associated with severity of mental health risk, finding levels of insomnia in the sample population higher than in the general population across risk categories. The impact of these findings on the measurement of other sleep characteristics, including SJL, was not discussed and may impact the validity of conclusions. Overall, neither this interplay nor direction of causality were explored or adequately controlled for in the reviewed studies. Given the cross-sectional design of all included papers, limited conclusions can be drawn relating to causality. Mental health conditions may directly impact on sleep or vis versa (Alvaro et al., 2013), or coping behaviours that emerge as a consequence of mental distress or inhibit sleep, such as ruminations, use of medication, substance misuse or alcohol, may have a disruptive effect on circadian preference and patterns (Adan et al., 2012; Vollmer et al., 2017), thus increasing SJL. There is also evidence in young people and adult populations of a bidirectional interaction between sleep disruption and mental health (Alvaro et al., 2013; Jansson-Fröjmark & Lindblom, 2008; Kaneita et al., 2009) which needs to be considered when drawing conclusions regarding the associations between SJL and mental health.

Equivocal findings may have emerged from reliance on self-report questions for both measures of mental health and SJL. SJL was predominantly assessed utilising self-report questions related to sleep onset and waking time through the MCTQ or bespoke questionnaires. Whilst the MCTQ is a well-used measure of chronotype, and could be taken as an objective measure given its use of retrospective recall of an individual's own sleep timings (Jankowski, 2015), there is limited work validating the measure with other objective measures of sleep timing (Di Milia et al., 2013; Jankowski, 2015), such as actigraphy or sleep diaries. Psychometric properties have not been completed for the MCTQ and it only has a weak relationship with other scales that measure circadian rhythmicity (Di Milia et al., 2013), questioning the former's reliability as a sole measure of circadian rhythm and sleep timings. Future research may benefit from comparing objective recording to self-report reporting of sleep onset/offset.

A range of mental health outcome measures were utilised; not all measures were validated for use within the sample populations. For example, the SPEQ was validated "in a general population sample of adolescents" aged 16-year-olds (Ronald et al., 2014), whereas Sheaves and colleagues study was undertaken amongst university students (IQR: 20–23). The STAI has been validated for people over the age of 15 – making it potentially unsuitable for 65% of participants in the Díaz-Morales (2015) study. An adaption of the SPAQ was developed for children and adolescents (SPAQ-CA; Swedo et al., 1995) which varies from the adult version in the assessment of GSS (Tonetti et al., 2012) however this was not used by either study investigating seasonal depression, despite both studies using the GSS for the assessment of depression severity. The use of unvalidated measures raises concerns about the accuracy and reliability of the resultant conclusions. The measures used also draw heavily on psychiatric understandings of distress characteristically identified in adults, with the majority of young people not meeting criteria of psychiatric mental illness (Patel et al., 2007). It may be useful to assess levels of distress more broadly in young people and behavioural measures may have increased utility, such as bullying behaviour (Kaltiala-Heino et al., 2000), substance misuse, and physical violence (Brooks et al., 2002). The level of distress in the sample population may not be adequately captured or may be

underreported due to the narrow focus of the outcome measures. Mental health has multifactorial influences in young people, including poverty, social connectedness, family conflict/breakdown, and parental mental health (Patel et al., 2007); ensuring such factors are controlled for is important when considering associations between SJL and mental health outcomes.

Several studies suggested significant differences between genders for SJL and mental health outcomes; with significant associations being found predominantly in female participants. This may be explained by the potential role of gender on sleep (Lindberg et al., 1997) and mental health (Bulhões et al., 2017; Patel et al., 2007). Differences in mental health experiences and expression (Bulhões et al., 2017; Patel et al., 2007) may impact study outcomes with young women more likely to disclose emotions (Breslau & Anthony, 2007) and young men more likely to display anger or emotional numbing (Bennett et al., 2005). In adults, women are more likely to experience distress through physiological changes (Bennett et al., 2005), sleep disturbances, and increased internalisation (Romans et al., 2007), whereas men display more behavioural expressions (Weller et al., 2006). Limited research has explored whether such gendered differences exist in young people, but it is usually assumed that this is the case (Bulhões et al., 2017; Weller et al., 2006). The outcome measures used in the selected studies may not adequately capture these subtle differences in expressions of distress.

5.1. Review limitations

Heterogeneity in methodological approaches to assess SJL and mental health outcomes precluded meta-analysis being undertaken in this review. Although a robust search strategy was employed to identify all relevant studies, it is possible that some studies have not been identified – particularly where SJL was not a primary outcome measure. Only a small number of studies were eligible for inclusion: all were cross-sectional, relied heavily on self-report measures, and were rated as moderate quality based on criteria assessing cross-sectional studies. The age group covered was broad and although under similar social pressures regarding sleep, exogenous factors that drive sleep in a 10-year-old may differ from a 24-year-old – particularly regarding autonomy and

responsibility for choices around sleep, as well as the shifting chronotype over this age range and varying sleep recommendations (Hirshkowitz et al., 2015). A narrower age category or comparing different age groups within the studies may have identified patterns specific to these age groups.

Indicators of mental health in young people may not always manifest in the emotional and functional symptomology characteristic of adult populations. Rather behavioural changes may be better markers of mental health in young people, particularly young men. Since this review limited search terms to diagnostic categories of mental health, studies which assessed SJL in comparison to behavioural indices were excluded.

These complex factors must be taken into account when assessing mental health and sleep. The interplay between variables, both exogenous and endogenous, may limit the usefulness of looking solely at SJL when assessing the relationship between sleep and mental health in young people.

5.2. Recommendations for future research and clinical practice

Future research should address the lack of standardised methodology for measuring SJL and mental health outcomes which limits the utility of research to inform social and health policies and interventions. The development of an agreed interdisciplinary core outcome set for use in sleep and mental health research appears key. A core outcome set should include objective as well as subjective measures to assess a range of sleep characteristics and psychosocial factors for evaluating the association between sleep and mental health in young people, and include a standardised measure and calculation for SJL, giving consideration to the implications suggested by Jankowski (2017). It should also include appropriate measures of mental health considering age, gender and cultural variations in assessing distress. Longitudinal studies to assess causality and whether the variation and high levels of SJL identified in young participants persists into adulthood are important, particularly given the potential links between SJL and depression suggested in this review and in adult studies (Levandovski et al., 2011), as well as with physical health risks (Rutters et al., 2014).

6. Conclusion

SJL is an emerging and complex sleep characteristic, thought to explain why individuals with late chronotype experience adverse health outcomes. SJL is highly prevalent in young people, and significant concerns have been raised regarding the association between sleep misalignment and mental health. This review suggests although the evidence for this association is equivocal there is a growing body of work to suggest an association with depression symptomology for young females. An overall standardised definition and measurement of SJL, and an agreed outcome set appropriate in terms of age, gender and cultural is of real importance for further meaningfully research.

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Part two: Empirical research report

EXAMINING THE ASSOCIATIONS BETWEEN SLEEP, SELF-COMPASSION AND DIABETES-RELATED DISTRESS FOR PEOPLE WITH TYPE 2 DIABETES MELLITUS

1. Abstract

Background: Adherence to a variety of health-promoting behaviours is important in managing type 2 diabetes mellitus (T2DM). Maintaining optimal sleep behaviours is associated with decreased T2DM risk and severity, and lower condition-related distress. Diabetes-related distress (DRD) may be influenced by self-regulation of health behaviours and emotions, and cultivating capacity for these psychological processes may reduce experiences of DRD. Sleep behaviours and self-compassion are suggested to act directly on physiological systems related to distress and T2DM, and indirectly upon emotional regulation and capacity for self-regulation. This study investigates relationships between sleep behaviours (sleep duration, social jetlag, and daytime sleepiness), DRD, and self-compassion.

Method: A cross-sectional study was undertaken as part of the Chronotype of Patients with Type 2 Diabetes and Effect on Glycaemic Control (CODEC) study. Data from self-report questionnaires, objective sleep measurements and demographic information were collected from 136 participants. Non-parametric correlations, hierarchical multiple regression and mediation analysis (with DRD as dependant variable) were completed with bootstrapping.

Results: Significant associations were identified between DRD and daytime sleepiness, social jetlag and total sleep duration. Significant associations were also identified between self-compassion and daytime sleepiness and weekend sleep duration, and between negative self-compassion traits (but not positive self-compassion traits) and daytime sleepiness and all sleep duration variables. A significant predictive role of daytime sleepiness, social jetlag, and self-compassion (via negative subscales) on DRD was identified; a partial mediating role of daytime sleepiness in the relationship between self-compassion and DRD was also present.

Discussion: This study indicates important relationships between sleep behaviours, self-compassion and DRD in a sample of patients with T2DM, and that self-compassion (particularly negative traits) and sleep behaviours play a role in predicting DRD. Psychological interventions for T2DM should include approaches focused on reducing negative self-compassion traits and improving sleep behaviours. Further work is needed to establish causality and long-term impact of these factors, and develop clinical resources to support the effective management of the psychological impact of T2DM.

2. Introduction

2.1. Sleep – a health behaviour

Sleep disturbances have been suggested to be internationally endemic (Stranges et al., 2012). Growing evidence suggests that sleep disturbances have significant consequences for short-term and long-term physical and mental health (Medic et al., 2017), including increased risk of developing chronic health conditions and increased difficulties with condition management (Buxton & Marcelli, 2010; Cappuccio et al., 2010; Shan et al., 2015). Despite this, many clinicians have limited knowledge of sleep as a health behaviour (Papp et al., 2002) and rarely include sleep behaviours in assessment and history taking (Sorscher, 2008). Sleep behaviours may be a modifiable risk factor, like diet and exercise, for mental and physical health (Perry et al., 2013); supporting patients to develop and adhere to health-promoting sleep behaviours may be an important intervention for reducing the impact of long-term health conditions. Indeed, a recent consensus statement (Watson et al., 2015) has recommended that individuals need to develop consistent sleep habits to "promote optimal health" and to reduce the risk of a range of cardiovascular and metabolic health conditions, including type two diabetes mellitus (T2DM).

2.2. Sleep and type two diabetes mellitus

The prevalence of T2DM has increased globally and it is estimated that this trend will continue (Olokoba et al., 2012; Wild et al., 2004). Lifestyle factors, such as diet, exercise and obesity, are established targets for preventative and ongoing management of T2DM (Asif, 2014), however adherence to optimal sleep behaviours are less commonly recommended despite evidence suggesting associations between sleep disruption and T2DM (Arora & Taheri, 2015; Beihl et al., 2009; Knutson et al., 2006; Yaggi et al., 2006).

Sleep deprivation studies indicate a relationship between lack of sleep and increased glucose intolerance (VanHelder et al., 1993), while longitudinal studies have concluded that both short (less than six hours) and long (over eight hours) sleep durations increase the risk of developing T2DM (Ayas et al., 2003; Gangwisch et al., 2007; Yaggi et al., 2006). Whilst sleep deprivation may increase the risk of T2DM, a range of sleep behaviours – including sleep

quality, sleep duration, and social jetlag (SJL, a misalignment of biological and social timing; Wittmann et al., 2006) – are also commonly experienced by individuals with a diagnosis of T2DM. These have implications for severity (Knutson et al., 2006), condition management (Chasens et al., 2013; Koopman et al., 2017), and other T2DM health-related measures, such as obesity (Parsons et al., 2015; Roenneberg et al., 2012) and cardiometabolic risk (Kantermann et al., 2013; Parsons et al., 2015; Wong et al., 2015). Suboptimal sleep quality and duration have also been linked with distress related to living with T2DM (Seixas et al., 2015; Seligowski et al., 2013; Zhou et al., 2017). This may potentially arise from the influence of sleep on physiological and neurological pathways relating to emotional regulation (Goldstein & Walker, 2014).

2.3. Diabetes, psychological wellbeing and distress

People with T2DM are required to undertake regular self-management behaviours, notably in respect of diet, exercise, and medication adherence, to regulate blood glucose level (HbA_{1c}). The demands of meeting these requirements may disproportionately affect an individual's psychological wellbeing (Barlow et al., 2002), with failure to sustain self-management behaviours leading to negative self-appraisal (Friis et al., 2015b). The psychological impact of T2DM has been conceptualised as diabetes-related distress (DRD).

DRD is a multi-faceted concept, distinct from depression. It relates to the complex and demanding activities that accompany living with a chronic illness (Polonsky et al., 2005) and the emotional reaction and appraisals that an individual may experience in relation to diagnosis, day to day management, and ongoing risks of the condition (Stanković et al., 2013). There is growing evidence that high levels of DRD have an adverse impact on self-management behaviours and diabetes outcomes (Fisher et al., 2010; Piette et al., 2004; Powers et al., 2017), and it has been suggested as a better predictor of HbA_{1c} than measures of depression (Friis et al., 2015b). This relationship may be influenced by the role of inter-related biological pathways associated with diabetes, psychological stress (Pickup, 2004), and sleep (Balbo et al., 2010).

For instance, irregularities in the hypothalamic-pituitary-adrenal (HPA) axis and increases in inflammatory biomarkers (such as interleukin-6) are associated with the stress response, the pathophysiology of T2DM at sub-clinical levels (Pickup, 2004), and sleep disruptions (Arnardottir et al., 2012; Balbo et al., 2010; Irwin et al., 2016). Distress and sleep behaviour may directly affect these physiological processes, but may also indirectly influence them through emotional regulation and self-regulation capacity acting upon adherence to health behaviours and perceptions of self and condition (Friis et al., 2015a; Paddison et al., 2010).

2.4. Self-regulation in diabetes-related distress

Successful self-regulation allows individual control over behaviours (Biber & Ellis, 2017) through processes and feedback loops influencing an individual's ability to set goals (such as management of T2DM), engage in goal-related behaviour/activities (such as sleep or diet behaviours), evaluate progress, and adjust behaviour (or goals) in light of this evaluation (Leventhal et al., 2003; Terry & Leary, 2011). Self-regulation can be disrupted by negative affect and self-appraisals (Sirois, 2015); given that managing T2DM can be demanding and stressful there is increased risk of negative perceptions and emotions. Those who are able to successfully regulate emotions should be more able to effectively self-regulate diabetes management behaviours though selection and maintenance of adaptive coping strategies and behaviours; thus reducing negative self-appraisals and experiences of condition-related distress (Cameron & Jago, 2008; Leventhal et al., 2003; Paddison et al., 2010). However, sustained emotional regulation (as is required to manage the complexities of T2DM) can deplete an individual's capacity to self-regulate, undermining adherence to health-promoting behaviours (Terry & Leary, 2011) and increasing risk of negative appraisals related to DRD.

DRD may be understood in the context of the association between ineffective emotional regulation and self-regulation. Psychological processes that promote emotional regulation, preserve the capacity for self-regulation, and influence selection of adaptive coping processes may affect perceptions and appraisal of any health threat and therefore emotional outcomes, such as DRD (Hagger &

Orbell, 2003). One such psychological construct, self-compassion (Neff, 2003b), has been suggested to have a role in utilising successful selection of coping strategies and enabling effective self-regulation and reduced condition-related distress (Biber & Ellis, 2017; Terry & Leary, 2011).

2.5. Self-compassion

Self-compassion is defined as the ability to take an approach to personal failure or difficulties that is kind, accepting and non-judgemental (Neff, 2003b). Increasingly examined in physical and mental health conditions (MacBeth & Gumley, 2012), it comprises three interlinked elements (Neff, 2003b, 2011): self-kindness, common humanity (seeing oneself in the broader context of others experiences), and mindfulness (being aware of one's own difficult feelings and thoughts in the present moment, without judging); with cultivation of these components mitigating impact of their obverse: self-judgement, isolation (a feeling of separateness from others) and over-identification (a magnification of attention on the self). A key feature of self-compassion is its influence on emotional regulation, and self-regulation of goal-orientated behaviours (Gilbert, 2009b; Neff et al., 2005; Neff et al., 2007) promoting activation of self-soothing (Gilbert, 2009a; Gilbert, 2009b).

This role in self-regulation and emotional regulation has clear applicability to health behaviours and outcomes (Sirois & Rowse, 2016), since a self-compassionate approach to health threats, such as T2DM, can promote successful condition management and limit condition-related distress via selection of adaptive rather than maladaptive strategies (Allen & Leary, 2010; Terry & Leary, 2011). For example, if an individual experiences failure to achieve a health-related goal (such as optimal HbA_{1c} level), low self-compassionate individuals may experience shame or self-criticism (Gilbert, 2009a) and discontinue health-promoting behaviour or use maladaptive strategies in response; alternatively, a self-compassionate individual may view this failure less negatively, treating themselves more kindly (self-kindness) since mistakes are part of universal human experience (common humanity) and are less enmeshed with thoughts and emotions of shame, frustration or sadness (mindfulness). Through this a more balanced and realistic approach to self-

management of T2DM could enable a more effective response to physical health threats (Terry et al., 2013), adherence to health-promoting behaviours (Adams & Leary, 2007; Magnus et al., 2010; Sirois et al., 2015), greater ability to adjust to change (Allen et al., 2012), improved overall well-being (Zessin et al., 2015), and effective management of the long-term health condition (Brion et al., 2014; Pinto-Gouveia et al., 2014; Wren et al., 2012).

Cultivating self-compassion in those with T2DM can permit acknowledgement of condition-related difficulties without self-judgement or becoming overwhelmed by condition demands (Neff, 2003b; Neff et al., 2007), thus mitigating DRD (Friis et al., 2016; Terry et al., 2013). Self-compassion may thus have a two-fold effect on self-regulation: improving adherence to self-management behaviour and improving emotional regulation (which improves self-management behaviour and reduces impact of condition-related distress).

2.6. Self-compassion and sleep

Self-compassion is argued to directly and indirectly affect the physiological pathways related to psychological stress, and in the pathophysiology of T2DM (Friis et al., 2015a); indeed higher self-compassion is associated with lower levels of interleukin-6 (Breines et al., 2014). Given the relationship identified between sleep and these physiological pathways (Arnardottir et al., 2012; Balbo et al., 2010; Goldstein & Walker, 2014; Irwin et al., 2016), self-compassion may also play an important role in sleep regulation behaviours and the emotional impact of sleep disturbances. Research to date suggests self-compassion has a positive impact on sleep habits (Kim & Ko, 2018; Sirois et al., 2015; Sirois et al., 2019) and is associated with sleep quality measures (Butz & Stahlberg, 2018; Greeson et al., 2014; Hu et al., 2018), albeit inconsistently (Kemper et al., 2015; Unger, 2016). These suggest self-compassion's role not only in indirect regulation of emotions linked to sleep loss, but also for intrinsic mechanisms related to self-regulation of sleep behaviours

2.7. Rationale

Health behaviours, such as diet and exercise, are recommended for the management of T2DM. Sleep behaviours as a modifiable risk factor is mooted, but further exploration is required to assess its role. The demands of self-

management of T2DM have are increasingly implicated in the development of DRD, with consequences for psychological well-being and diabetes outcomes. Sleep behaviours also appear associated with DRD with higher levels of distress associated with poor sleep quality and greater sleep disturbances.

Self-regulatory processes, particularly emotional regulation, appear to play a role in adherence to health behaviours and can mitigate risk of psychological distress. Cultivation of self-compassion as an intervention for diabetes management can improve outcomes and psychological wellbeing (Friis et al., 2015b, 2016) through its intrinsic regulatory function, driven by developing three related positive traits (self-kindness, common humanity, and mindfulness) and reducing their obverse (Neff, 2003b). Whilst optimal sleep behaviours are associated with lower levels of DRD (Seixas et al., 2015; Seligowski et al., 2013; Zhou et al., 2017), and higher self-compassion is associated with better sleep quality (Butz & Stahlberg, 2018; Greeson et al., 2014; Hu et al., 2018; Kemper et al., 2015; Unger, 2016), other facets of sleep, such as duration, SJL, and daytime sleepiness, have yet to receive similar explorations, although similar relationships might be expected.

Despite intuitive overlaps between metabolic pathways, sleep, emotional regulation and self-compassion, the relationship of these within a population of people with T2DM has received little attention. Therefore, this study built on previous research in diabetes management to investigate the relationships between DRD, sleep behaviours, and self-compassion (and its component parts), and the interacting relationships of these components of diabetes management.

2.8. Research questions

This study sought to examine associations between behavioural sleep characteristics (daytime sleepiness, sleep duration, and SJL), self-compassion and the psychological impact of diabetes management, as measured by the Diabetes Distress Scale, in a population with T2DM. Secondary to this, the study sought to identify if sleep behaviours moderated or mediated the relationship between self-compassion and DRD.

The following research hypotheses were thus made:

Hypothesis 1: Self-compassion would be significantly correlated with sleep measures (positively with sleep duration; and negatively with other measures); and significantly and negatively correlated with DRD.

Hypothesis 2: DRD would be significantly correlated with sleep measures (negatively with sleep duration and positively with other measures).

Hypothesis 3: Self-compassion and its constituent subscales would predict DRD.

Hypothesis 4: Sleep outcome measures would predict DRD;

Hypothesis 5: Sleep behaviours would have a mediation effect on the relationship between self-compassion (total self-compassion and constituent subscales) and DRD.

3. Method

3.1. Study design

This nested study was a secondary analysis utilising data collected as part of the Chronotype of Patients with Type 2 Diabetes and Effect on Glycaemic Control (CODEC) study, a cross-sectional study with a range of self-report and objective outcome measures relating to glycaemic control and chronotype in people with established T2DM (Clinicaltrials.gov, 2018).

3.2. Procedure

As part of the CODEC study, participants attended data collection research clinics. Data was collected by clinical research staff, through a range of methods including clinical interview, anthropometric and clinical data (i.e. blood (venous) for biomarkers and glycaemic analysis), and participant completion of self-report questionnaires (Clinicaltrials.gov, 2018; Appendix H). Participants included in the current analysis attended data collection clinics held between May 2017 and May 2018.

Participant data was collated by CODEC research staff and held on a central database. Variables relating to the current analysis were extracted from the central database by CODEC research staff to form the database used in this analysis. Participants were anonymised prior to data extraction. Only those datasets related to participants who completed the outcome measures of interest at the time of extraction were included in this analysis. Appendix I outlines further details of research procedure and the relationship between the current study and the CODEC study.

3.3. Participants

The CODEC study included adult participants (age 18–75 years) with an established diagnosis of T2DM (longer than six months), no diagnosis of sleep disorder (excluding Obstructive Sleep Apnoea (OSA)), and competency in English to participate in the research tasks.

Participants were included in the current study if they had given fully informed verbal and written consent to participate in both the full CODEC study and an optional sub-study. This sub-study involved completion of additional self-report

questionnaires and collection of objective sleep measures via a wearable actigraphy sensor (Section 3.6.3). These were completed at home during the week following the data collection clinic. Only datasets with all outcome variables of interest completed were included in the current analysis. All participant information was anonymised prior to inclusion in the current study database.

3.4. Sample size

Sample size was estimated following guidance for determining sample size to detect a mediated effect (Fritz & MacKinnon, 2007) using bias-corrected bootstrapping. Previous literature reporting associations between self-compassion and health behaviour was used to estimate the effect size (α) between the predictor variable (self-compassion) and the mediator variable (sleep measures), and the effect size (β) between the mediator variable and outcome variable (DRD). Therefore according to Fritz and MacKinnon (2007) to achieve a power of 0.8, with $\alpha = 0.29$ and $\beta = 0.39$, the minimum sample size required was 116.

3.5. Ethical approval

Approval for the current study was obtained from the University of Leicester Psychology Ethics Sub-committee and the Health Research Authority (Appendix J). As the study utilised anonymous data from an ongoing research project, already approved by the Health Research Authority and NHS Ethics, further NHS ethical approval and approval from the host NHS Trust Research and Development department was not required. Participants included in this study were informed via the CODEC participant information sheet that data may be included in further research. A data access agreement was completed to grant access to study data (Appendix J.4).

3.6. Equipment and materials

Data for this analysis was drawn from sources completed during CODEC data collection. Only demographic and outcome variables required for the current analysis were transferred to the current study database.

3.6.1. Demographic information

Demographic information was collected at the data collection research clinic via questionnaires completed by study research staff and participants, and collated in the clinical record form. Variables included in the current study were: age, gender, employment status, and year of T2DM diagnosis (used to calculate the duration of T2DM diagnosis and age of onset). Height and weight (used to calculate BMI) were measured as part of a health and employment interview undertaken at the data collection research clinic. Glycated haemoglobin (HbA_{1c}), a standardised measure of the amount of glucose carried in haemoglobin, was measured from an assay of a venous blood sample taken during the data collection research clinic by a research nurse.

3.6.2. Self-report measures

3.6.2.1. Diabetes Distress Scale (DDS; Polonsky et al., 2005)

The DDS is a 17-item self-report measure of DRD (Appendix K.1); assessing four domains: emotional, physician-related, regimen-related, and interpersonal distress. The severity of an individual's problems over the last month are rated using a six-point Likert-like scale (1 = "not a problem" to 6 = "A very serious problem"). No items relate to sleep difficulties. Item scores were summed and averaged to give a total mean score (range: 1–6) with higher values indicating greater distress. A consistent structure and good internal reliability and validity have been demonstrated (Polonsky et al., 2005) with similar research studies suggesting Cronbach's α being 0.89 (Friis et al., 2016). Scores were totalled to give a continuous variable. The clinical cut offs are: "Little or no distress" (DDS <2.0), "Moderate distress" (DDS = 2.0–2.9), and "High distress" (DDS ≥3) (Fisher et al., 2012).

3.6.2.2. Self-compassion Scale (SCS; Neff, 2003a)

The SCS is a self-report questionnaire measuring individual self-compassion. It comprises 26 statements (Appendix K.2) which are rated on a five-point Likert-type scale (1 = "Almost never" to 5 = "Almost always"). Statements factor onto six subscales: three positive (self-kindness, common humanity, mindfulness) and three complementary negative subscales (self-judgement, isolation, and over-identification). Statements are scored (with negative scale statements

reverse-coded). An average score was calculated for each individual subscale and a mean full scale score (Total self-compassion) comprising all subscales were taken to represent an individual's self-compassion (range: 1–5). Higher scores relate to higher levels of self-compassion.

The psychometric properties of the SCS have yet to be specifically examined in chronic health condition populations, however studies in student, community and clinical populations have demonstrated good construct reliability (Neff et al., 2017), predictive validity (Neff et al., 2007), and internal reliability (Neff, 2016). Reliability in diabetes population was reported as excellent (α = 0.91; Friis et al., 2016).

A two-factor model (self-compassion and self-criticism) has also been suggested (Costa et al., 2016; López et al., 2015), however recent work across a diverse population by the scale's author concluded that use of the SCS with the original mean full scale and six subscale scores is the most robust measure of self-compassion (Neff et al., 2018). Therefore the original mean scale scores outlined by Neff were used in this study.

3.6.2.3. Epworth Sleepiness Scale (ESS; Johns, 1991)

The Epworth Sleepiness Scale is a self-report questionnaire to measure daytime sleepiness. It assesses participant retrospective recall of dozing behaviour rather than subjective sleepiness (Johns, 2009). Eight items (Appendix K.3) are rated on a four-point scale regarding likelihood of falling asleep whilst undertaking different daytime activities (0 = "Would never doze" to 3 = "High change of dozing"). These items were then summed (range: 0–24). The clinical cut offs are: "Normal daytime sleepiness" (0–10); "Mild daytime sleepiness" (11–12); "Excessive daytime sleepiness" (≥13) (Johns, 2019).

3.6.3. Objective sleep measures

Participants wore a GENEActiv accelerometer device on their non-dominant wrist for up to eight (24-hour) consecutive days. The device was fitted at the data collection clinic and was not removed until the end of the wear period. Participants returned the device to the research team in a pre-paid envelope provided with the device. Outputs from the GeneActiv device included onset

and end of sleep periods and total sleep duration (van Hees et al., 2015) and these measures were used to calculate:

3.6.3.1. Sleep duration

Total sleep time between sleep onset and waking was recorded and used to calculate three variables: mean sleep duration for the whole wear period, mean for week days, and mean for weekend sleep.

3.6.3.2. Mid-point of sleep

The half way point between sleep onset and sleep end was calculated to provide three variables: Mean mid-point of sleep across the wear period (total), mean mid-point of sleep on week days (MSW), and mean mid-point of sleep on weekend days (MSF). Mid-point sleep variables were not used in the final analyses.

3.6.3.3. Social jetlag

Mid-point of sleep on weekend and week days were used to calculate absolute SJL as: SJL = |MSF-MSW| (Wittmann et al., 2006). Due to insufficient data for mid-point of sleep on work and free days, only 30 participants had variables for sleep-corrected SJL (Jankowski, 2017), a measure of SJL which takes into account individual chronotype and weekend oversleep, therefore this was not included in the current analysis.

3.7. Statistical analysis

Data was collated and additional variables calculated using Microsoft Excel software before the complete dataset was inputted into IBM Statistical Package for Social Sciences (SPSS) for Windows Version 25 to complete analysis. A total of 156 participants completed the self-compassion scale questionnaire. Participants were excluded from further analysis if other outcome variables were missing (n = 20).

3.7.1. Preliminary analysis

Descriptive statistics were undertaken to calculate participant characteristics, with mean and standard deviation (SD) for normally-distributed continuous

variables; median and interquartile range for non-normally distributed continuous variables; and percentages for categorical variables.

All data was screened for statistical assumptions. Checks for normality were undertaken by examination of histograms, Q-Q and P-P scatter graphs. This identified variables which were not normally distributed. Square-root transformations were undertaken on variables which exhibited skew. Successful square-root transformations were undertaken on variables, age, SJL, BMI and duration of diabetes, which were used in subsequent analysis. However, transformation (neither square-root nor log) did not improve the distribution of DDS, ESS, and negative self-compassion subscale data (Appendix L). As DDS was the primary dependant variable, non-parametric analysis and bootstrapping (2000 samples) were undertaken to reduce the effect of non-normal distribution and outliers (Field, 2013).

3.7.2. Hypothesis testing

Two-tailed correlation analysis using Kendall's Tau-b with bias corrected and accelerated bootstrapping was completed between all variables. Hierarchical multiple regressions with bias corrected and accelerated bootstrapping were used to determine the contribution of sleep variables (ESS, Sleep Duration and SJL; added separately) and self-compassion on the outcome/dependant variable, DRD (as measured by mean DDS). A second set of hierarchical multiple regressions (alternative model) with bias corrected and accelerated bootstrapping were used to estimate the contribution of each of the self-compassion subscales alongside sleep variables on DRD. Due to associations identified between demographic variables and dependant variable, and in line with Friis et al. (2015b), age and gender alongside BMI and onset of diabetes were controlled for at step one in all linear regressions. To each hierarchical regression, a separate sleep variable (step two) and total self-compassion, or the six subscales (step three) were added to assess main effects. A final step to assess any interaction effect (step four) was included in the total self-compassion model. An interaction term was created between self-compassion and sleep variables (centred around the variable mean to reduce multicollinearity) to assess if the interaction between self-compassionate traits

and sleep behaviours explained unique variance in DRD (Aiken et al., 1991; Field, 2013). A separate mediation analysis was completed using PROCESS V.3 (Hayes, 2014; model 4), with 95% bootstrap confidence intervals (5000 sample) to assess the indirect effect of self-compassion on DRD via sleep behaviours.

4. Results

4.1. Sample characteristics

One hundred thirty-six participants with complete dataset were included in this study. All participants had an established diagnosis of T2DM (>6 months) and did not have a diagnosis of a sleep disorder (excluding OSA). Table 5 summarises descriptive statistics of demographic variables.

Table 5: Descriptive statistics of demographic variables

Variable	n =136	
Sex	Male	64% (n = 87)
	Female	36% (n = 49)
Age (years)	Median = 65.5 (IQR: 59.25 – 71.0)	
Employment status	Retired	55.9% (n = 76)
	Employed	31.6% (n = 43)
	Volunteer	7.4% (n = 10)
	Unemployed	5.1% (n = 7)
BMI	Median = 29.95 (IQR: 27.15 – 33.68)	
Diabetes Duration (years)	Median = 10 (IQR: 5.0 – 16.75)	
Age of Onset (years)	Mean = 52 (SD: 10.35)	
HbA1c (%)	Mean = 7.40 (SD: 0.95)	

Participants' age ranged between 41 and 75 years, with 50% of the sample over 65.5 years old. BMI ranged between 19 and 44, with the majority (89.7%; n = 122) falling within the overweight or obese categories. Biological measure of diabetes management indicated that 61.8% (n = 84) of the sample population had sub-optimal level of HbA1c (≥7.0; range: 5.2 – 9.9). The majority of participants did not reach clinical threshold for DRD (DDS <2; 64%, n = 87). Moderate to high levels of self-compassion (mean score ≥2.5) were reported in 86% (n = 117) of the sample population. The majority of the sample population reported relatively healthy sleeping habits with 59.6% (n = 81) and 55.1% (n = 75) achieving at least seven hours sleep on weekdays and weekends, respectively, with only ten participants recording sleep durations below 5.5 hours. Clinically relevant daytime sleepiness (ESS ≥11) affected 25.7% (n = 35) of the sample population, and 17.6% (n = 24) experiencing an average SJL of one hour or more.

4.2. Relationship between variables

Table 6 summarises the correlation coefficient for associations for dependant and predictor variables, as well as the measures of central tendency for each. Table 7 summarises correlations for demographic variables.

4.2.1. Self-compassion and diabetes-related distress

As predicted in hypothesis one, overall self-compassion was moderately, negatively and significantly related to DDS score. This suggests that as self-compassion scores decrease, DRD increases. Negative subscales of the SCS showed a stronger association with DDS score than positive subscales, suggesting these have a greater influence within the construct of self-compassion in the relationship with psychological distress related to diabetes self-management. Negative correlations occurred between negative subscales, however because reverse scoring was used on these scales to enable a total score to be calculated, this relationship can be interpreted as increases in negative traits relate to increased DDS scores.

In addition, age of diabetes diagnosis (but not duration of diagnosis) was significantly associated and correlated negatively with DDS and positively with self-compassion, indicating that those who are diagnosed with T2DM earlier in life may have poorer emotional regulation (lower self-compassion, higher level of DRD).

4.2.2. Sleep behaviour, self-compassion and diabetes-related distress

All sleep measures were associated with self-compassion in the direction predicted; however, only daytime sleepiness and weekend duration reached >.05 significance level. In contrast, all sleep characteristics, except SJL, were significantly associated with negative self-compassion subscales.

As predicted in hypothesis two, all measures of sleep were associated with DDS in the direction predicted; however only daytime sleepiness, TSD and SJL reached >.05 significance level.

Table 6: Kendall's Tau Correlation Coefficients (τ) for dependant and predictor variables

Variable	Median /Mean	IQR/ SD	1 DDS	2 Mean SCS	3 SCS SK	4 SCS SJ	5 SCS CH	6 SCS I	7 SCS M	8 SCS OI	9 ESS	10 TSD	11 WeSD	12 WdSD
1. Diabetes-related Distress (DDS)	1.47	1.12-2.46	1.00											
2. Total mean SCS	3.27	0.69	-.30** (-.40, -.19)	1.00										
3. Self-Kindness (SCS SK)	2.55	1.0	-.04	.51** (.42, .60)	1.00									
4. Self-Judgement (SCS SJ)	4.0	2.8-4.75	-.43** (-.53, -.32)	.37** (.25, .47)	.03	1.00								
5. Common humanity (SCS CH)	2.79	1.19	.13* (.01,.26)	.30** (.18, .40)	.39** (.29, .48)	-.28** (-.41, -.15)	1.00							
6. Isolation (SCS I)	4.0	3.0-4.75	-.46** (-.56, -.35)	.42** (.30, .53)	.04	.63** (.55, .70)	-.17** (-.29, -.04)	1.00						
7. Mindfulness (SCS M)	3.13	1.05	-.03	.53** (.44, .60)	.53** (.42, .63)	-0.06	.57** (.47, .66)	-0.00	1.00					
8. Over-identifying (SCS OI)	4.0	2.75-4.5	-.47** (-.55, -.38)	.47** (.36, .57)	.07	.60** (.51, .67)	-.15* (-.27, -.02)	.56** (.46, .65)	.11	1.00				
9. ESS	7.0	4.0-11.0	.27** (.15, .38)	-.20** (-.32, -.08)	-.07	-.20** (-.33, -.08)	.01	-.23** (-.35, -0.10)	-.10	-.25** (-.36, -.14)	1.00			
10. Total Sleep Duration (TSD)	441.85	70.59	-.12* (-.23, -.01)	.09	.04	.13* (.02, .24)	.15	.14* (.03, .25)	.03	.12* (.01, .23)	-.07	1.00		
11. Weekend Sleep Duration (WeSD)	453.75	80.69	-.09	.158** (.04, .28)	.12†	.14* (.03, .25)	.03	.13* (.02, .23)	.11	.12* (.01, .23)	-.06	.60** (.52, .67)	1.00	
12. Weekday Sleep Duration (WdSD)	436.26	76.61	-.11	0.06	0.00	.13* (.01, .24)	-.08	.14* (.02, .25)	-.01	.12†	-.05	.84** (.79, .88)	.44** (.34, .54)	1.00
13. SJL	24.00	10.25 - 51.75	.13* (.02, .25)	-0.10	-0.01	-0.11	-.03	-.09	-.06	-.10	.05	-.10	-.02	-.11

N=136; All rounded to 2dp. Statistical significance: *p <.05; **p<.001; BCa bootstrap 95% confidence intervals (CI) reported in brackets; † Violation of Bootstrapped CI; SCS=Self-Compassion Scale; DDS=Diabetes Distress Scale; ESS=Epworth Sleepiness Scale (daytime sleepiness); SJL=Social jetlag.

Table 7: Kendall's Tau Correlation Coefficients (τ) for demographic variables					
	DDS	**Total mean SCS**	**ESS**	**Sleep Duration (TSD)**	**SJL**
Age	-.24** (-.34,-.14)	.14* (.03, .25)	-.06	.11	-.16** (-.26, -.04)
Sex	.15* (.01; .29)	-.13	.01	.04	-.07
BMI	.16** (.04, .27)	-.11	.21** (.09, .32)	-.06	.03
Diabetes duration	-.02	-.02	.12	.02	-.04
Age of Type 2 diabetes diagnosis	-.21** (-.31; -.11)	.14* (.02, .26)	-.13* (-.24, -.02)	.08	-.01
HbA_{1c}	.28** (.15; .40)	-.23** (-.35; -.11)	.04	-.09	.04

N=136; Kendall's Tau Correlation Coefficients (τ) are presented. All rounded to 2dp. Statistical significance: *p <.05; **p<.001; BCa bootstrap 95% confidence intervals reported in brackets for significant results. DDS=Diabetes Distress Scale; SCS=Self-Compassion Scale; ESS=Epworth Sleepiness Scale (daytime sleepiness); SJL= Social jetlag; TSD=Total Sleep Duration

4.3. Predictors of diabetes-related distress

Hypotheses three and four suggested that self-compassion and behavioural sleep characteristics (sleep duration, daytime sleepiness, and SJL) would be predictive of DRD and therefore hierarchical linear regressions were modelled using these as predictors. It was also proposed that the individual subscales of self-compassion would all have a predictive influence on DRD; therefore in the alternative model, the total self-compassion variable was replaced with the individual mean subscale scores. Hierarchical linear regression results are summarised in Table 8 (total self-compassion model) and Table 9 (alternative model with self-compassion subscales).

4.3.1. Control variables

At step one (Table 8 and 9) for the total self-compassion model and alternative model, the control variables demonstrated statistical significance in predicting DRD ($F[4,131] = 5.49$, $R^2 = 0.14$, $p<.001$). Age significantly accounted for 6.0% of the unique variance in DRD ($\beta = -.33$, $p = .01$), indicating that younger age predicts a higher level of DRD. Gender, BMI, and age of diabetes diagnosis were not significant predictors of DRD (p values >.05).

4.3.2. Sleep behaviours

At step two (Table 8 and 9) for the total self-compassion model and alternative model, age remained a significant predictor of DRD. The addition of daytime sleepiness and SJL, but not sleep duration variables, produced statistically significant changes in R^2 for DRD.

Daytime sleepiness explained 13.4% unique variance in DRD ($\Delta F[5,130] = 24.08$, $p<.001$). Self-reported levels of daytime sleepiness had a significant predictive role in DRD, with the standardised coefficient ($\beta = .23$) suggesting for 1 SD increase in daytime sleepiness, DRD increased by 0.23 SD (when other predictors are held at constant). SJL added 3% unique variance ($\Delta F[5,130] = 4.76$, $p<.001$) with the standardised coefficient ($\beta = .18$) indicating that for 1 SD increase in SJL, DRD increases by 0.18 SD (when other predictors are held at constant).

4.3.3. Total self-compassion

At step three (Table 8), the addition of total self-compassion produced statistically significant changes in R^2 for DRD in all models, explaining an additional 13-14% variance for the overall models including sleep duration (e.g. Total Sleep Duration: $\Delta R^2 = 0.14$; $\Delta F[6,129] = 24.00$, $p<.001$) and SJL ($\Delta R^2 = 0.13$; $\Delta F[6,129] = 24.97$, $p<.001$). With self-compassion included in the model, the unique variance of sleep characteristics was reduced, with sleep duration accounting for less than 1% unique variance ($p>.05$), and SJL reduced to a non-significant 2%.

The addition of total self-compassion had a lesser impact when added to the daytime sleepiness model. Self-compassion explains an additional 9% variance in DRD ($\Delta R^2 = 0.09$; $\Delta F[6,129] = 17.57$, $p<.001$), with daytime sleepiness still explaining 8% of the variance ($\beta = .32$; $Part^2 = 0.08$; $p<.001$) and age explaining 6% of the variance ($\beta = -.36$; $Part^2 = 0.06$; $p=.001$) in DRD. Step three suggested that total self-compassion is a significant predictor of DRD when demographic variables are controlled for, however, unlike other sleep behaviours, daytime sleepiness has an equally predictive role in distress related to diabetes management ($\beta = .32$ for both predictors) in this sample. No interaction effect was identified at step four.

4.3.4. Self-compassion subscales

When the self-compassion subscales were substituted into the model at step 3 (Table 9), significant changes to R^2 for DRD were again seen across all models. Use of the six individual subscales explained more overall variance in DRD than total self-compassion. Significant changes in R^2 indicated the individual subscales explained an additional 32-33% variance in models including sleep duration (e.g.: Total sleep duration: $\Delta R^2 = 0.32$; $\Delta F[11,124] = 12.72$, $p<.001$) and including SJL ($\Delta R^2 = 0.32$; $\Delta F[11,124] = 12.91$, $p<.001$), and 24% variance in the daytime sleepiness model ($\Delta R^2 = 0.24$; $\Delta F[11,124] = 10.10$, $p<.001$). Positive subscales of the self-compassion scale were not unique or significant predictors of DRD (all $p>.05$), this may be due to overlap with other self-compassion subscales in the model. Only negative subscales offered unique explanation of the variance in DRD, with only “over-identification” subscale

showing a significant (p=.01-.02) unique contribution to the explanation of variance in DRD regardless of inclusion of sleep behaviour.

The use of the subscales of self-compassion reduced the contribution of SJL in predicting distress and indicated it to be a non-significant factor in predicting DRD; whilst sleep duration remained non-significant in predicting DRD. Age and daytime sleepiness remained significant predictors of DRD. In the daytime sleepiness model, “over-identification” made the strongest unique contribution ($\beta = -.30$; $Part^2 = 0.02$; $p<.001$) to the explanation of DRD variance, followed by daytime sleepiness ($\beta = .23$; $Part^2 = 0.04$; $p<.001$), and age ($\beta = -.28$; $Part^2 = 0.02$; $p <.001$); whilst “Self-judgement” ($\beta = -.16$; $Part^2 = 0.01$; $p>.05$) and “isolation” ($\beta = -.16$; $Part^2 = 0.01$; $p>.05$) made a small and non-significant contribution.

Step three of the alternative model suggested that use of the total self-compassion remains the best overall significant predictor of DRD when demographic variables are controlled for, alongside daytime sleepiness and age, however the variance in diabetes-related scores may be best predicted by changes in the negative subscales, particularly “over-identification".

Table 8: Linear model of predictors of diabetes-related distress (self-compassion and sleep characteristics).

Step		Unstandardised		Standardised	Model Summary statistics
		B	SE	β	
1	Age	-0.04* (-0.07, -0.01)	0.01	-.33	R^2 = 0.14 Adjusted R^2 = 0.12 ΔF = 5.49**
	Sex	0.07 (-0.22, 0.36)	0.16	.04	
	BMI	0.24 (-0.12, 0.60)	0.18	.12	
	Diabetes age	0.002 (-0.02, 0.02)	0.01	.02	
2	ESS	0.08** (0.05, 0.11)	0.02	.40	R^2 = 0.28 Adjusted R^2 = 0.25 Δ R^2 = 0.13 ΔF = 24.08**
3	ESS	0.06** (0.03, 0.10)	0.02	.32	R^2 = 0.36 Adjusted R^2 = 0.33 ΔR^2 = 0.09 ΔF = 17.57**
	Self-Compassion (SC)	-0.43** (-0.61, -0.25)	0.10	-.32	
4	ESS	0.06** (0.03, 0.10)	0.02	.32	R^2 = 0.37 Adjusted R^2 = 0.33 ΔR^2 = 0.003 ΔF = 0.51
	SC	-0.42** (-0.59, -0.22)	0.10	-.31	
	SC * ESS	-0.01 (-0.06, 0.02)	0.02	-.05	
2	Total Sleep Duration (TSD)	-0.002 (-0.004, 0.001)	0.001	-.12	R^2 = 0.16 Adjusted R^2 = 0.12 ΔR^2 = 0.01 ΔF = 1.96
3	TSD	-0.001 (-0.003, 0.001)	0.001	-.07	R^2 = 0.29 Adjusted R^2 = 0.26 ΔR^2 = 0.13 ΔF = 24.00**
	SC	-0.52** (-0.72,-0.32)	0.11	-.39	
4	TSD	-0.001 (-0.003, 0.001)	0.001	-.08	R^2 = 0.29 Adjusted R^2 = 0.25 ΔR^2 = 0.000 ΔF = 0.03
	SC	-0.52** (-0.72,-0.31)	0.11	-.39	
	SC*TSD	0.00 (-0.01, 0.004)	0.002	-.01	
2	Weekend Sleep Duration (WeSD)	-0.001 (-0.003, 0.001)	0.001	-.06	R^2 = 0.15 Adjusted R^2 = 0.11 ΔR^2 = 0.003 ΔF = 0.52
3	WeSD	0.00 (-0.001, 0.002)	0.001	.02	R^2 = 0.28 Adjusted R^2 = 0.25 ΔR^2 = 0.14 ΔF = 14.73**
	SC	-0.54** (-0.74, -0.30)	0.11	-.40	
4	WeSD	0.00 (-0.001, 0.002)	0.001	.02	R^2 = 0.29 Adjusted R^2 = 0.25 ΔR^2 = 0.000 ΔF = 0.03
	SC	-0.55** (-0.75, -0.31)	0.11	-.40	
	SC* WeSD	0.00 (-0.003, 0.01)	0.001	.02	

2	Weekday Sleep Duration (WdSD)	-0.001 (-0.004, 0.001)	0.001	-.12	R^2 = 0.16 Adjusted R^2 = 0.13 ΔR^2 = 0.01 ΔF = 2.15
3	WdSD	-0.001 (-0.003, 0.001)	0.001	-.10	R^2 = 0.29 Adjusted R^2 = 0.26 ΔR^2 = 0.14 ΔF = 24.67**
	SC	-0.52** (-0.72, -0.32)	0.11	-.39	
4	WdSD	-0.001 (-0.003, 0.001)	0.001	-.10	R^2 = 0.29 Adjusted R^2 = 0.25 ΔR^2 = 0.000 ΔF = 0.07
	SC	-0.53** (-0.74, -0.29)	0.11	-.39	
	SC* WdSD	0.00 (-0.004, 0.003)	0.002	-.02	
2	Social jetlag (SJL)	0.05* (0.003, 0.11)	0.03	.18	R^2 = 0.17 Adjusted R^2 = 0.14 ΔR^2 = 0.03 ΔF = 4.76*
3	SJL	0.05 (-0.01, 0.10)	0.03	.16	R^2 = 0.31 Adjusted R^2 = 0.28 ΔR^2 = 0.13 ΔF = 24.97**
	SC	-0.52** (-0.72, -0.32)	0.10	-.39	
4	SJL	0.04 (-0.01, 0.10)	0.03	.15	R^2 = 0.31 Adjusted R^2 = 0.28 ΔR^2 = 0.005 ΔF = 0.84
	SC	-0.52** (-0.75, -0.31)	0.11	-.39	
	SC*SJL	0.03 (-0.04, 0.11)	0.04	.07	

Based on 2000 bootstrap samples. All figures rounded to 2dp. BCa bootstrap 95% confidence intervals reported in brackets. Statistical significance: *p<.05; **p<.001. Abbreviations: ESS=Epworth Sleepiness Scale (Daytime sleepiness); SC=total self-compassion; TSD= Total Sleep Duration; WeSD=Weekend Sleep Duration; WdSD=Weekday Sleep Duration; SJL= Social jetlag

Table 9: Linear model of predictors of diabetes-related distress (self-compassion subscales, daytime sleepiness and social jetlag).

Step		Unstandardised		Standardised	Model Summary statistics
		B	SE	β	
1	Age	-0.04* (-0.07, -0.01)	0.01	-.33	R^2=0.14 Adjusted R^2=0.12 ΔF=5.49**
	Sex	0.07 (-0.22,0.36)	0.16	.04	
	BMI	0.24 (-0.12, 0.60)	0.18	.12	
	Diabetes age	0.002 (-0.02, 0.02)	0.01	.02	
2	ESS	0.08** (0.05, 0.11)	0.02	.40	R^2=0.28 Adjusted R^2=0.25 ΔR^2=0.13 ΔF=24.08**
3	ESS	0.05** (0.02, 0.07)	0.01	.23	R^2=0.52 Adjusted R^2=0.47 ΔR^2=0.24 ΔF=10.10**
	Self-Kindness	0.03 (-0.13, 0.19)	0.08	.03	
	Self-Judgement	-0.14 (-0.34, 0.07)	0.11	-.16	
	Common Humanity	-0.02 (-0.16, 0.11)	0.08	-.02	
	Isolation	-0.13 (-0.34, 0.06)	0.11	-.16	
	Mindfulness	0.04 (-0.19, 0.27)	0.11	.04	
	Over-Identification	-0.24* (-0.45, -0.02)	0.11	-.30	
2	SJL	0.05* (0.003, 0.10)	0.03	.18	R^2=0.17 Adjusted R^2=0.14 ΔR^2=0.03 ΔF=4.76*
3	SJL	0.04 (-0.01, 0.07)	0.02	.12	R^2=0.49 Adjusted R^2=0.45 ΔR^2=0.32 ΔF=12.91**
	Self-Kindness	0.03 (-0.13, 0.20)	0.09	.03	
	Self-Judgement	-0.12 (-0.33, 0.10)	0.11	-.14	
	Common Humanity	0.002 (-0.14, 0.12)	0.08	.003	
	Isolation	-0.17 (-0.39, 0.04)	0.12	-.20	
	Mindfulness	0.01 (-0.21, 0.24)	0.11	.01	
	Over-Identification	-0.28 (-0.48, -0.05)	0.11	-.34	

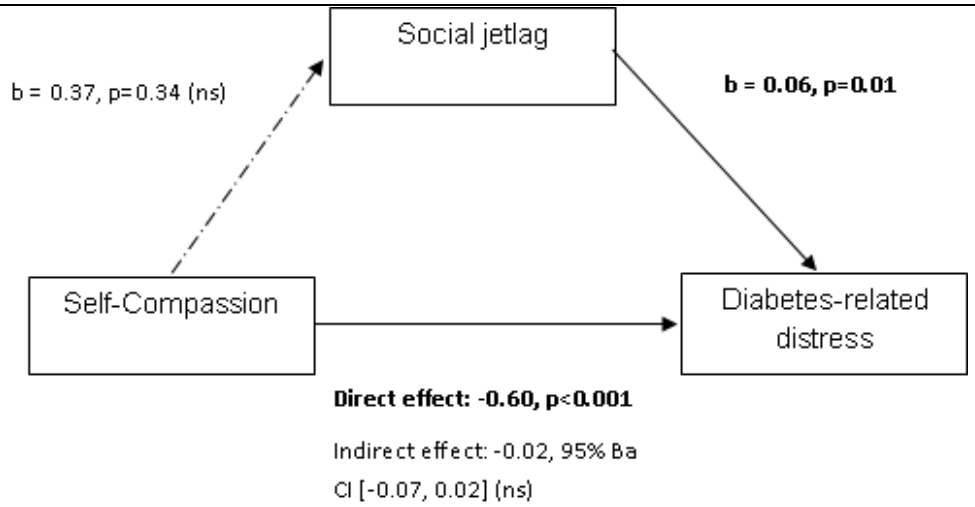
Based on 2000 bootstrap samples. All figures rounded to 2dp**.** BCa bootstrap 95% confidence intervals reported in brackets. Statistical significance: *p<.05; **p<.001**.** Abbreviations: ESS=Epworth Sleepiness Scale (Daytime sleepiness); SJL=Social jetlag

4.4. Mediation

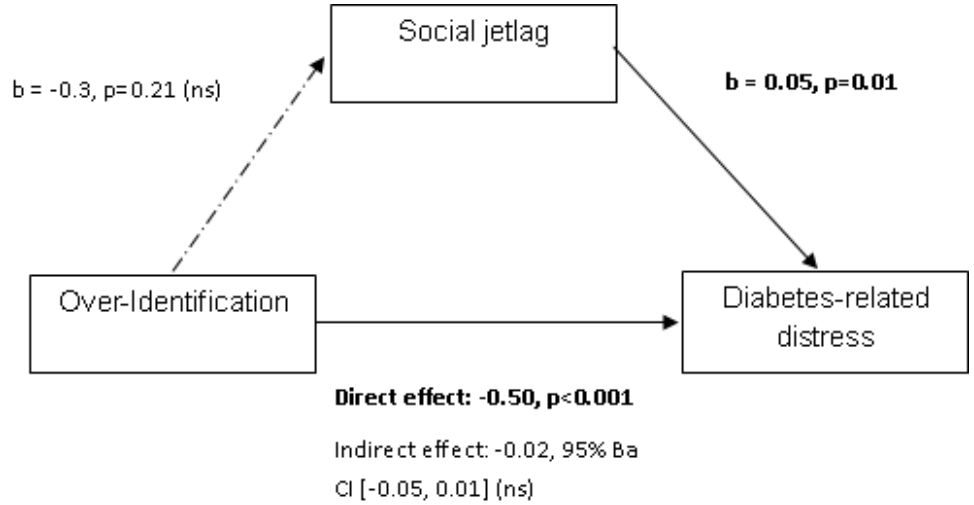
As only daytime sleepiness and SJL were identified as predictors of DRD in this sample, only these variables were added to the mediation model. No significant indirect effect of self-compassion through SJL was identified, b= -0.02, 95% Ba CI [-.07, 0.2] (Figure 2). However, a significant indirect effect of self-compassion on DRD through level of daytime sleepiness was identified, b= -0.12, 95% Ba CI [-0.23,-0.04] (Figure 3), which represents a medium effect size, κ^2 = -0.09, 95% Ba CI [-0.17,-0.03]. When separate self-compassion subscales were included in the mediation model, a significant direct effect of the negative subscales, but not the positive subscales was identified; also a significant indirect effect of the negative subscales, but not the positive subscales, through daytime sleepiness was identified (Figure 3).

4.5. Diagnostic assessment

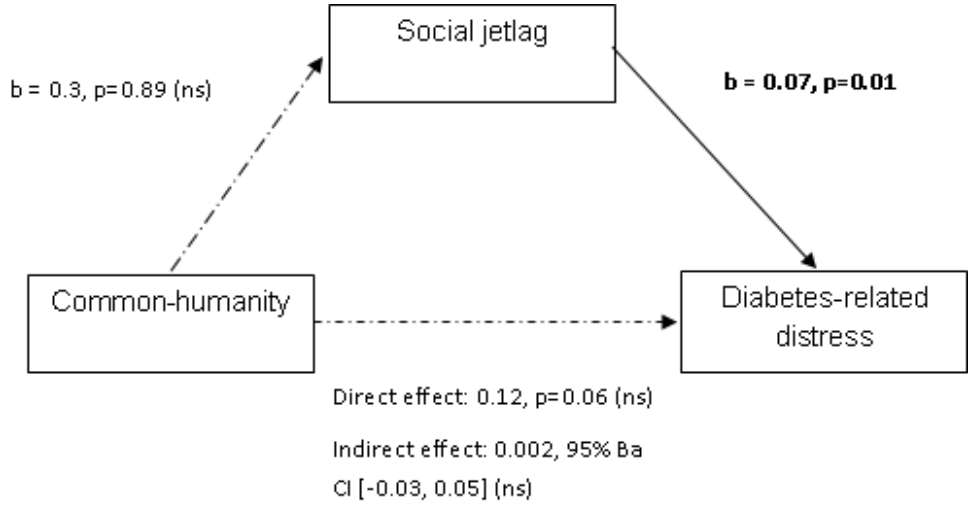
Due to the non-normal distribution of the dependant variable and related nature of the predictor variables in the alternative model, further diagnostic assessment was carried out to check validity of the models. Mean and standard deviation for standardised residuals were within range of acceptability for normal distribution (Mean=0, SD: 0.96). No standardised residual was greater than 3.29 or less than -3.29 (Field, 2013) and less than 1% of standardised residuals fell above 3.0 or below -3.0 (Pallant, 2016). Cook's Distance ranged between 0–0.18; as the maximum did not exceed 1.0, this suggested that outlying residuals did not have excessive influence on the overall model (Tabachnick & Fidell, 2001). For each predictor variable in model one, tolerance factors ranged from 0.49–0.97 and variance inflation factors (VIF) ranged from 1.04–2.01. Tolerance factors fell (0.25–0.94) and VIF increased (1.06–4.09) in the alternative model, as would be expected given the related nature of the SCS subscales. Despite this, as tolerance factors did not fall below 0.2 and VIF did not go above 10 (Field, 2013; Menard, 1995) no concern regarding multicollinearity between predictor variables were indicated in the model.



a) Total self-compassion and social jetlag predict diabetes-related distress, social jetlag does not mediated this relationship

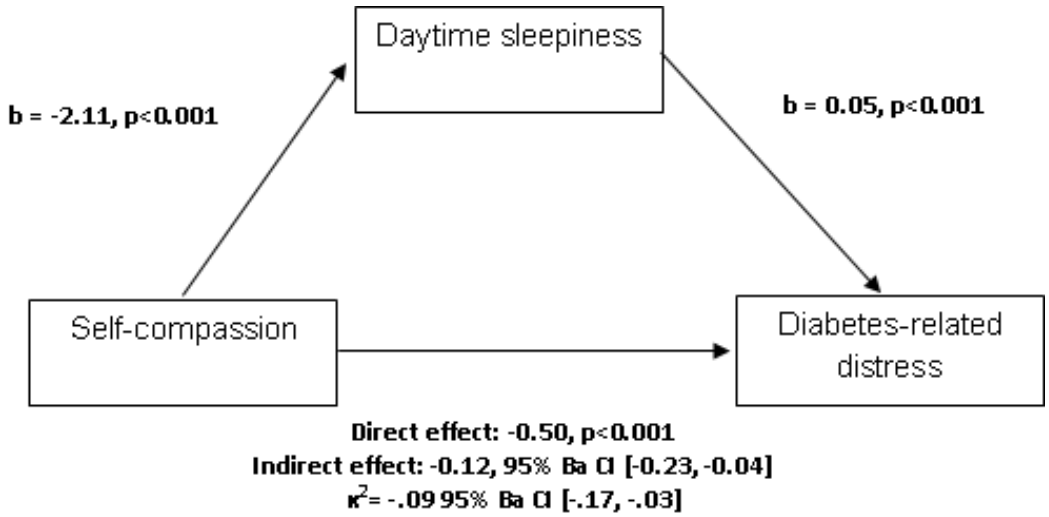


b) Over-identification (and other negative subscales) and social jetlag predict diabetes-related distress, social jetlag does not mediated this relationship

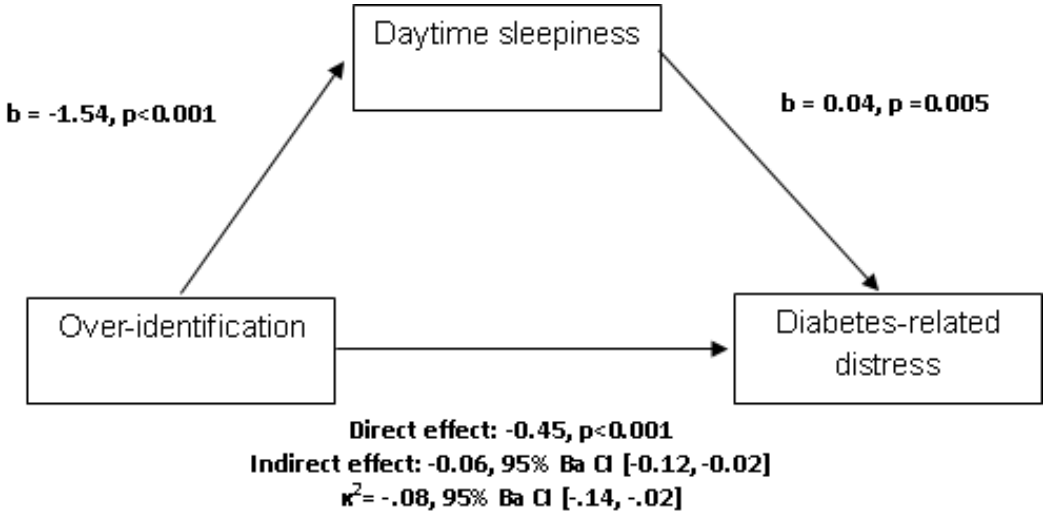


c) Common-humanity (and other positive subscales) did not predict diabetes-related distress or social jetlag

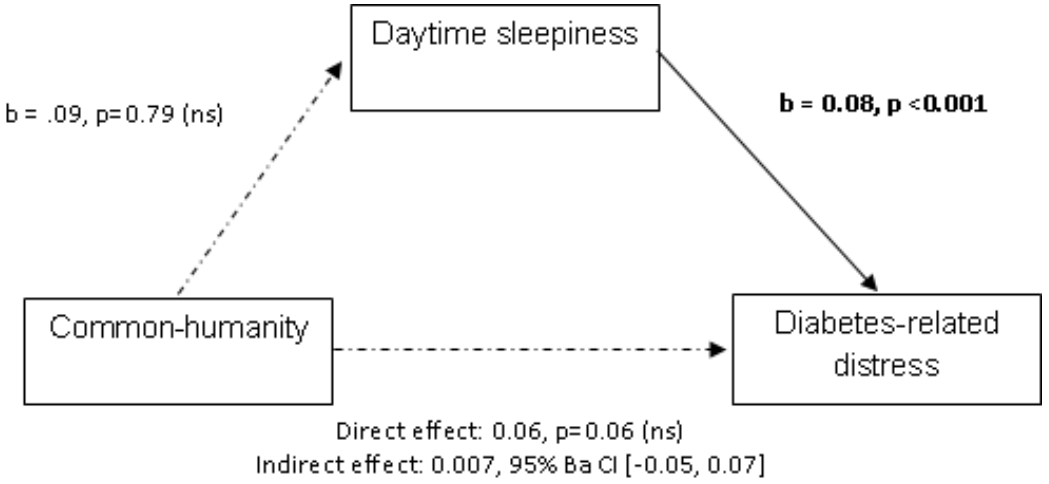
Figure 2: Mediation model of self-compassion as predictor of diabetes-related distress, through relationship with social jetlag.



a) Total self-compassion predicts diabetes-related distress, mediated by daytime sleepiness



b) Over-identification (and other negative subscales) predicts diabetes-related distress, mediated by daytime sleepiness



c) Common-humanity (and other positive subscales) did not predict diabetes-related distress or daytime sleepiness

Figure 3: Mediation model of self-compassion as predictor of diabetes-related distress, through relationship with daytime sleepiness.

5. Discussion

This cross-sectional, multi-variable analysis examined the associations between psychological distress related to diabetes self-management (DRD), sleep behaviours, and the psychological construct of self-compassion among participants with T2DM. Key findings of this research are:

- significant associations identified between DRD and sleep behaviour outcomes: daytime sleepiness, SJL and TSD;
- significant associations identified between self-compassion and daytime sleepiness and WeSD, and between negative self-compassion traits (but not positive self-compassion traits) and daytime sleepiness and all sleep duration variables;
- significant predictive role of daytime sleepiness, and to a lesser extent SJL, on DRD;
- confirmed relationship between self-compassion and DRD, and identified a greater predictive role of negative subscales (particularly over-identification) compared to positive traits of self-compassion;
- identified a partial mediating role of daytime sleepiness in the relationship between self-compassion and DRD.

5.1. Diabetes-related distress and sleep behaviours

In the current study, both self-report and objective measures were collected for a range of sleep behaviours. Significant associations were identified between DRD and sleep behaviours, both self-reported and objectively measured. Small to moderate, and significant associations were identified between higher reported DRD and higher daytime sleepiness, reduced total sleep duration, and greater discrepancy between mid-point of sleep on weekends and weekdays (SJL). Previous work (Zhou et al., 2017) identified an association between DRD and sleep duration, which was not as strongly evidenced in the current study, possibly due to the smaller sample size in this analysis. However, Zhou and colleagues included the culturally appropriate daytime nap as well as night time sleep within the measure of sleep time, which makes the measurements less comparable, and perhaps more directly links with experiences of daytime sleepiness, itself identified here as a strong predictor of DRD.

5.2. Self-compassion and sleep behaviours

Significant association were identified between total self-compassion and daytime sleepiness and weekend sleep duration; with negative subscales of self-compassion being associated with all sleep duration variables and daytime sleepiness. SJL was not associated with self-compassion variables.

Given the different relationships observed between self-compassion and the different sleep behaviour outcomes, self-compassion may differentially effect sleep behaviours and their impact on DRD (Hu et al., 2018). Hu and colleagues identified that self-compassion acted via stress either directly or indirectly depending on whether the sleep outcome was a “purely sleep” variable or was related to mood or emotions. No direct measures of sleep quality, sleep ruminations, or insomnia were included in the current study and this may have provided further evidence for the differing associations of self-compassion with sleep.

The difference in relationship may also result from how a self-compassionate approach interacts with sleep behaviours associated with the outcome reported. For example, the observed lack of association between self-compassion and SJL, despite both separately predicting DRD, may result from differing approaches to sleep behaviour elicited by self-compassion traits. For some individuals a self-compassionate approach may imply maintaining regular sleep and wakening patterns (reducing SJL), whereas for others it may be to increase oversleep on non-working days (increasing SJL). As such, highly self-compassionate people could experience high or low SJL depending on their preferred approach.

5.3. Predictor of diabetes-related distress: self-compassion

A moderate and significant association was also identified between DRD and total self-compassion, with increased self-compassion scores being predictive of a reduction in DRD, consistent with Friis et al. (2016), who identified a decrease in DRD related to increased self-compassion following a self-compassion educational group for individuals with type 1 and type 2 diabetes mellitus. Although those with higher DRD may have less capacity to undertake self-compassionate approaches, the work of Friis and colleagues suggests a

causal link between increasing self-compassion and a reduction in DRD. The current study builds on and extended these findings within a T2DM sample by identifying unique and significant associations only between the negative subscales of the self-compassion scale and DRD.

Although the total self-compassion scale score provided the most explanation of variance in DDS scores in hierarchical regressions, the alternative hierarchical regression model and mediation models (including the subscales) suggested that negative subscale scores, particularly over-identification (where an individual is enmeshed with their thoughts and feelings, as opposed to a mindful approach), have a direct effect on DRD and provides the most unique explanation of variance.

As this is a cross-sectional study, causality cannot be inferred; however as with Friis and colleagues (2016), these findings suggest that targeting interventions for DRD through reducing self-critical appraisals may have greatest impact.

5.4. Predictor of diabetes-related distress: daytime sleepiness and social jetlag

Despite the significant and direct effect of self-compassion on DRD, daytime sleepiness was identified as an equal contributor to explaining the variation in DDS scores, even when other variables were controlled for. It was also identified as a partial mediator, significantly accounting for some of the relationship between self-compassion and DRD. Those with low self-compassion and high levels of daytime sleepiness may experience a greater level of DRD, compared with those reporting only lower self-compassion. Given the strong relationship between self-compassion and well-being (Neely et al., 2009; Zessin et al., 2015), this finding parallels Seligowski et al. (2013) which identified a partial mediating role of sleep quality in the relationship between depression and anxiety symptoms with diabetes-related quality of life measures. Daytime sleepiness may have had a moderate incremental effect on DRD in addition to emotional regulation accounted for by self-compassion alone.

The questionnaire used to measure daytime sleepiness in this study is a validated self-report measure of how likely someone is to fall asleep during different common activities, and is understood to measure the influence of

night-time sleep disruption on daytime activities. However, it does not capture psychosocial facets such as overall attention, motivation, quality of life and emotional regulation (Johns, 2009) also potentially impinging on experience of daytime sleepiness. These psychosocial factors are perhaps more akin to the self-regulation factors related to self-compassion and DRD, than the objective sleep processes like sleep duration and SJL.

SJL was also identified as a predictor of DRD however when self-compassion was added to the model, SJL no longer played a unique or significant role in predicting DRD.

DRD is a multi-faceted measure of psychological impact and confidence in the self-management of diabetes, influencing an individual's ability to self-manage and effecting condition-related outcomes, such as HbA_{1c} (Fisher et al., 2010). Although self-compassion, sleep behaviours and age were significant predictors of DRD, these variables accounted for less than 30% of the variance in DDS scores, suggesting other factors can predict risk and impact on psychological well-being and self-management of T2DM. In addition, the 17-item DDS was not examined regarding its four subscales and doing so could have offered specific targets for clinical interventions and support. Despite this, the current study has identified the important role of self-compassion, particularly negative traits, in identifying and managing DRD with its effect improved by the reduction of suboptimal sleep behaviours.

5.5. Sleep and diabetes management

The role of sleep in predicting and influencing diabetes symptoms (Gangwisch et al., 2007; Zhu et al., 2018) and long-term management (Chasens et al., 2013; Knutson et al., 2006) was not directly assessed in this study. We confirmed significant, strong correlations between HbA_{1c} with DRD and self-compassion seen in previous work (Friis et al., 2015b). However in the current study, these significant correlations were not identified between sleep measures and HbA_{1c}; it may be that the interaction between sleep, distress and self-compassion are of importance to HbA_{1c} and overall management of diabetes. Further investigation of these interactions should develop the evidence base in this area.

5.6. Interaction of sleep behaviours and distress

Depression and anxiety are common co-morbid conditions with T2DM (Katon et al., 2007; Lloyd et al., 2000) and sleep disruption is commonly a symptom of affective disorders. DRD has been identified as strongly associated with depressive symptoms (Fisher et al., 2010; Powers et al., 2017) and an interaction effect between sleep quality and depression on diabetes-related quality of life has also been identified (Zhang et al., 2016). It is therefore unclear whether sleep behaviours result from DRD and emotional dysregulation, rather than sleep having a causal impact on the distress associated with living with T2DM, or if there is an additional role of depression in sleep or distress. This cannot be ascertained in the current study as the cross-sectional nature prevents causality being inferred; also, depression was not included as a variable and therefore was not controlled for. Therefore the inter-relation between mental ill-health, sleep and distress related to self-management were not accounted for in the analysis, but future work may wish to distinguish between these two related but distinct psychological constructs of negative affect.

5.7. Theoretical and clinical implications

Previous work has suggested that optimal sleep behaviours can reduce risk and improve outcomes in T2DM, and the current work confirms that increased levels of daytime sleepiness and SJL are associated with lower scores on the DDS. It also gives further support to the direct effect of self-compassion on emotional regulation related to DRD, even controlling for demographic variables. These findings suggest that daytime sleepiness, SJL and self-compassion are potential modifiable targets to improve distress associated with managing T2DM.

As such, when working with individuals with T2DM, a thorough assessment of risk of distress and poor self-management should include evaluation of sleep behaviours, particularly daytime sleepiness and regularity of sleep patterns. An assessment of self-critical traits and approaches to health, based on the negative subscales of the self-compassion scale, could be developed for use

with this patient group to identify individuals who may benefit from early psychological intervention to support self-management of T2DM.

Clinical Psychologists working with individuals and groups with T2DM who are experiencing negative affect and psychological distress related to self-management of diabetes should consider targeted psychological treatment interventions (such as compassion focused therapy or mindfulness approaches) augmented by sleep hygiene interventions. The development and evaluation of such interventions particularly with a clear emphasis on the reduction of negative, self-critical traits will be necessary for supporting clinicians working with this clinical population.

Finally, self-compassionate skills training and information on sleep hygiene and optimal sleep behaviours should be included in diabetes education and intervention programmes alongside traditional management strategies for T2DM, such as weight management, dietary change, and physical exercise. This should be available to all those with a T2DM diagnosis as a potential preventative strategy to reduce psychological impact of living with a complex and demanding long-term health condition.

5.8. Limitations and strengths

There are a number of limitations to this study. Firstly, with a cross-sectional design, causation cannot be affirmed and it is not possible to assess if the relationships identified endure over time. Many of the variables were gained from self-reported measures; although all measures were validated in this population, this collection method may affect the reliability of reported outcomes.

The majority of participants demonstrated suboptimal glycaemic control (HbA_{1c}≥7.0%), however other variables suggested the sample population could be considered to have good self-regulation, with majority of participants having healthy sleep behaviours, low levels of DRD, and moderate to high levels of self-compassion. This may be related to recruitment bias, with those who have better self-regulation, education, or are in another way demographically different more likely (and possibly more able) to volunteer for research (Glasgow et al.,

1996; Martinson et al., 2010). Further work to address and categorise non-responders should be considered.

Many of the variables generated from ordinal data showed significant skew, and were unable to be corrected via statistical transformation, possibly contributing bias and error to the statistical analysis. However, strategies employed to mitigate bias alongside diagnostic review of the statistical data suggested no causes for concern.

The appropriateness of measures within the current sample population should be taken into account when interpreting the results. SJL has been identified as less common within a retired population due to less social influence on sleep patterns (Foster et al., 2013; Roenneberg et al., 2012); in this sample population, 56% of participants were retired and therefore any effect of SJL may not be identified or relevant in this sample. Daytime sleepiness may be more notable in this sample population due to the inclusion of participants with an OSA diagnosis, the impact on sleep and daily activity of diabetes co-morbidities, an older sample population, as well as other social factors which were not accounted for in the current analysis.

In addition, no diabetes-related complications or symptoms were controlled for in this study; future work should consider the implications of concurrent physical and mental health conditions.

Although the sample size provided sufficient power for analyses undertaken, further analysis was precluded due to the small sample size. It was not possible to categorise and compare participants by levels of sleep duration due to the small number of participants in the highest and lowest range.

Many of these limitations were related to the current study using data from a larger existing research study. This resulted in limited opportunity to input into participant recruitment, participant inclusion/exclusion criteria, and the outcome measures utilised. Future research considering sleep behaviours, self-compassion, and DRD would benefit from considering how cognitions, beliefs about health and sleep behaviours may impact on the inter-relationships between these variables, as well as further consideration of associations with

demographics, co-morbidities, and other diabetes-related self-management behaviours.

Despite these limitations this research is based within a relatively new field of intersecting research areas, and supports the growing evidence base for the role of developing self-compassionate approaches and targeted sleep behaviour interventions in the medical and psychological management of T2DM. This study was part of a wider study of sleep in a diverse population of people with T2DM, covering a range of outcome measures including objective sleep measures to reduce impact of bias relating to self-report sleep outcomes. Under the CODEC protocol, standard operating procedures were used for data collection and collating; all research staff received training to standardise data collection; and data was double entered (with 10% source verified) to reduce error in collating the dataset. Participants had an established diagnosis of T2DM and so would have been living with the demands of the condition and therefore levels of DRD would also be established.

5.9. Direction for further research

Future work should build in longitudinal, follow-up and interventional approaches to assess causality and long-term impact of self-compassion, sleep behaviours, and DRD. It is also important to design research which specifically includes suboptimal sleep behaviours so that a fuller analysis of the relationship between DRD, self-compassion and extremes of sleep can be assessed. The addition of other control variables as well as use of chronotype and the sleep-corrected SJL measure is also important in identifying those who would benefit from interventions including self-compassion and sleep. Investigating associations within age categories may also be beneficial, given the rise of T2DM diagnosis in younger age groups (Lascar et al, 2018); here younger age was significantly associated with higher DRD rating, lower total self-compassion, and higher SJL.

Due to the identification of self-compassionate and self-critical approaches as predictive of daytime sleepiness and DRD, qualitative studies would be valuable to assess beliefs about sleep in this clinical population and the impact of these

on self-regulation of sleep behaviours and self-management of health behaviours.

6. Conclusion

This UK based cross-sectional study has added to the evidence base that self-compassion and sleep behaviours play a role in predicting the severity of distress related to T2DM. Further work is needed to establish causality and long-term impact of these factors, as well as to develop clinical resources to support the effective management of the medical and psychological impact of this complex and challenging condition.

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Appendices

A. Glossary of sleep terms

All adapted from Roenneberg and Merrow (2016) unless otherwise stated.

Actigraphy: a valid, objective and non-invasive method of monitoring limb movement which is used to determine periods of activity and rest cycles in humans (Stone & Ancoli-Israel, 2011; p 1668).

Alignment: when circadian rhythms are synchronised to 24-hour solar clock and also to other phase relationships.

Misalignment: when circadian rhythms are out of sync with 24-hour solar clock and/or other phase relationships. This usually applies to the relationship between and influence on individual internal circadian patterns, the timing of the physical environment (such as daylight), and the social environment (such as work timings), such as mistiming of sleep or feeding in relation to day/night cycle due to shift work.

Chronotype: the individual differences in timing of circadian rhythm patterns driven by entrainment and genetics. These individual differences are seen as earlier or later phase differences between circadian rhythms which influence preferences for timing of daily activities. Often known as morningness and eveningness, or Larks and Owls (Roenneberg & Merrow, 2016; Walker, 2017).

Circadian clock/pacemaker: the physiological, intrinsic timing systems of organisms at a cellular level which drives the generation of daily rhythms. These run automatically even in the absence of zeitgebers. Cellular clocks form networks that programme circadian patterning throughout the organism (National Institute of General Medical Sciences, 2017; Roenneberg & Merrow, 2016).

Circadian rhythms: physiological, psychological and behavioural changes that follow a daily cycle. These respond primarily to changes in light and dark in the environment and are found in most living organisms (National Institute of General Medical Sciences, 2017).

Daytime Sleepiness: “a propensity to become drowsy or to fall asleep when the intention and expectation is to remain awake and alert” (Johns, 2009).

Entrainment: the process whereby the circadian clock synchronises to zeitgebers.

Free-run: in a constant environment (i.e., without zeitgeber signals), circadian patterns continue to occur through internal processes that maintain a self-producing rhythm.

Phase relationship: the relationship between different oscillating patterns of periodic cycles or waveforms. For example the rises and falls of a rhythmic cycle may oscillate concurrently, in anti-phase, or lag each other.

SCN: the suprachiasmatic nucleus (“master clock”) is situated within the hypothalamus receiving information regarding light levels from the eyes. It coordinates all cellular circadian clocks through entrainment by light/dark signals (National Institute of General Medical Sciences, 2017; Roenneberg & Merrow, 2016).

Sleep pressure: an increasing physiological desire to sleep facilitated by the accumulation of chemicals (including adenosine) over the course of awake periods; the levels fall over periods of sleep (Walker, 2017).

Social jetlag (SJL): the misalignment between different sleep behaviours on workdays and work-free days. SJL is calculated as the absolute difference between the midpoints of sleep on work- and free days.

Solar clock: the cycle of light and dark in line with the positioning of the sun.

Zeitgeber: regularly occurring environmental signals (usually cyclical), such as day light, meal times, and work patterns.

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B. Anonymity checklist *

	Checked in Abstract	Checked in main text	Checked in appendices
Pseudonym or false initials used	N/A	N/A	N/A
Reference to pseudonym/false initials as a footnote	N/A	N/A	N/A
Removed any reference to names of Trusts/hospitals/clinics/services (including letterhead if including letters in appendices)	✓	✓	✓
Removed any reference to names/specific dates of birth/specific date of clinical appointments/addresses/ location of client(s), participant(s), relatives, caregivers, and supervisor(s). [For research thesis – supervisors can be named in the research thesis "acknowledgements" section]	✓	✓	✓
Removed/altered references to client(s) jobs/professions/nationality where this may potentially identify them. [For research thesis – removed potential for an individual research participant to be identifiable (e.g., by a colleague of the participant who might read the thesis on the internet and be able to identify a participant using a combination of the participants specific job title, role, age, and gender)]	✓	✓	✓
Removed any information that may identify the trainee (consult with course staff if this will detract from the points the trainee is making)	✓	✓	✓
No Tippex or other method has been used to obliterate the original text – unless the paper is subsequently photocopied and the trainee has ensured that the obliterated text cannot be read	✓	✓	✓
The "find and replace" function in word processing has been used to check the assignment for use of client(s) names/other confidential information	✓	✓	✓

C. Author Guidelines for Target Journal *

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Updated 28-01-2019

D. PRISMA checklist: Moher et al. (2009)

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	12
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	13
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	17
Objectives	4	Provide an explicit statement of questions being addressed	17
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed, and, if available, provide registration information including registration number.	18
Eligibility criteria	6	Specify study characteristics and report characteristics used as criteria for eligibility, giving rationale.	18-19
Information sources	7	Describe all information sources in the search and date last searched.	18
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix E
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	18 – 19, Figure 1
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	19 & Appendix F
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	Appendix F

Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	19-20
Summary measures	13	State the principal summary measures.	N/A
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	N/A
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	19-20
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	21 & Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted and provide the citations.	23, Table 1 & 2
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	26 & Table 3
Results of individual studies	20	For all outcomes considered, present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	28-31 & Table 4
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	34-38, 39
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	38-39
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	40

E. Systematic Search Strategy (September 2018)

#1	(Social Jet Lag) OR (Social jetlag)
#2	(sleep debt) OR (sleep-debt)
#3	(sleep deficit)
#4	(sleep misalignment) OR (circadian misalignment)
#5	morningness OR eveningness OR chronotyp*
#6	chronodisruption OR chronobiology OR (sleep compensation) or (catch up sleep)
#7	#1 OR #2 OR #3 OR #4 OR #5 OR #6
#8	(mental health) OR (mental illness) OR (mental ill health)
#9	depressi* OR dysthymic OR melanchol*
#10	anxi*
#11	(psychological wellbeing) OR (psychological well-being)
#12	*stress
#13	#8 OR #9 OR #10 OR #11 OR #12
#14	Adolescen*
#15	Teen*
#16	“Youth” OR “Young” OR “Young Adult*”
#17	Child*
#18	Juvenile*
#19	#14 OR #15 OR #16 OR #17 OR #18
#20	#7 AND #13 AND #19

F. Data Extraction Tool

<table>
<tr><td colspan="3">Title:</td></tr>
<tr><td colspan="3">Authors:</td></tr>
<tr><td colspan="2">Publication Date:</td><td>Journal:</td></tr>
<tr><td>Volume:</td><td>Issue:</td><td>Page:</td></tr>
<tr><td colspan="3">Background/ Rationale:</td></tr>
<tr><td colspan="3">Objectives/hypothesis:</td></tr>
<tr><td colspan="3">Participant recruitment/sampling:</td></tr>
<tr><td colspan="3">Location, dates, season:</td></tr>
<tr><td colspan="2">Participant total:
Withdrawals:
Are non- participants accounted for?</td><td rowspan="2">Participant demographics:
Sex:
Age:
Ethnicity:
Education:
Co-morbidity:
Other:</td></tr>
<tr><td colspan="2">Clinical group/non-clinical group:

Setting:</td></tr>
<tr><td colspan="3">Participant inclusion/exclusion criteria:</td></tr>
<tr><td colspan="3">Study design/methodology:</td></tr>
<tr><td colspan="3">Measure of Social Jetlag (what source? Standardised or novel? Psychometric properties?)</td></tr>
<tr><td colspan="3">Calculation of Social Jetlag and Mid-sleep point?</td></tr>
<tr><td colspan="3">Mental Health measure(s)?</td></tr>
<tr><td colspan="3">Other measures: (what source? Standardised or novel? Psychometric properties?)</td></tr>
<tr><td colspan="3">Analysis: (Describes statistical methods? Methods used to examine interactions and subgroups? How was missing data addressed? How were demographics accounted for?)</td></tr>
<tr><td colspan="3">Results:
SJL:
Mental health:
SJL and MH:
Other:</td></tr>
<tr><td colspan="3">Conclusions:</td></tr>
<tr><td colspan="3">Limitations:</td></tr>
<tr><td colspan="3">Other comments?</td></tr>
</table>

G. Appraisal of Cross-sectional Studies (AXIS) questions

Taken from Downes et al. (2016), Table 2

	Yes	No	Do not know/ comment
Introduction			
1. Were the aims/objectives of the study clear?			
Methods			
2. Was the study design appropriate for the stated aim(s)?			
3. Was the sample size justified?			
4. Was the target/reference population clearly defined? (Is it clear who the research was about?)			
5. Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?			
6. Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?			
7. Were measures undertaken to address and categorise non-responders?			
8. Were the risk factor and outcome variables measured appropriate to the aims of the study?			
9. Were the risk factors and outcome variables measured correctly using instruments/measures that had been trialled, piloted or published previously?			
10. Is it clear what was used to determined statistical significance and /or precision estimates?			
11. Were the methods (including statistical methods) sufficiently described to enable them to be repeated?			
Results			
12. Were the basic data adequately described?			
13. Does the response rate raise concerns about non-response bias?			
14. If appropriate, was information about non-responders described?			
15. Were the results internally consistent?			
16. Were the results for the analyses described in the methods, presented?			
Discussion			
17. Were the authors' discussions and conclusions justified by the results?			
18. Were the limitations of the study discussed?			
Other			
19. Were there any funding sources or conflict of interest that may affect the authors' interpretation of the results?			
20. Was ethical approval or consent of participants attained?			

H. Details of CODEC study

Taken from Clinicaltrials.gov

Study number: NCT02973412;

Study Description

The aim of this study is to explore the associations between chronotype and glycaemic control, cardiometabolic health and other lifestyle factors.

Study Design

Study Type: Observational

Observational Model: Case-Only

Time Perspective: Cross-Sectional

Official Title: Chronotype of Patients With Type 2 Diabetes and Effect on Glycaemic Control: The CODEC Study

Study Start Date: December 2016

Estimated Study Completion Date: June 2021

Outcome Measures

Primary Outcome Measures:

Choronotype (As defined by the MEQ chronotype categories)

HbA1C level (measured from a blood sample.)

Secondary Outcome Measures:

Mid-Sleep Time (MSF) - on both free and work days

Glucose (mmol/L)

Insulin (mmol/L)

C-Peptide (ng/mL (conventional units), or nmol/L (SI))

Total cholesterol levels (mmol/L)

HDL-cholesterol levels (mmol/L)

LDL-cholesterol levels (mmol/L)

Trigylceride levels(mmol/L)

Liver function test (including AST, ALT, ALP and albumin)

Weight (Kg)

Body composition via bioimpedance

Height (cm)

Blood pressure (mmHg)

hsCRP (mg/L) - Biomarker of inflammation

Levels of physical activity (Recall Physical Activity Questionnaire, RPAQ)

Duration of diabetes

Consumption of Pathogen Associated Molecular Patterns (PAMPs)

Sleep duration (self-report)

Physical function (self - report)

Physical performance (Short Physical Performance Battery (SPPB) plus hand grip)

Objective measures of physical activity and sleep duration (GENEActiv)

Energy intake (24-hour dietary recall (DR))

Clock genes (whole blood sample)

Temporal distribution of calorie intake (determined by 24-hr food recall)

Prevalence of each chronotype category

IL-6 (pg/ml) - Biomarker of inflammation

Leptin (ng/L) - Biomarker of inflammation

Adiponectin (pg/ml) - Biomarker of inflammation

Age of onset

Age at which the participant was diagnosed with Type 2 Diabetes

Eligibility Criteria

Inclusion Criteria:

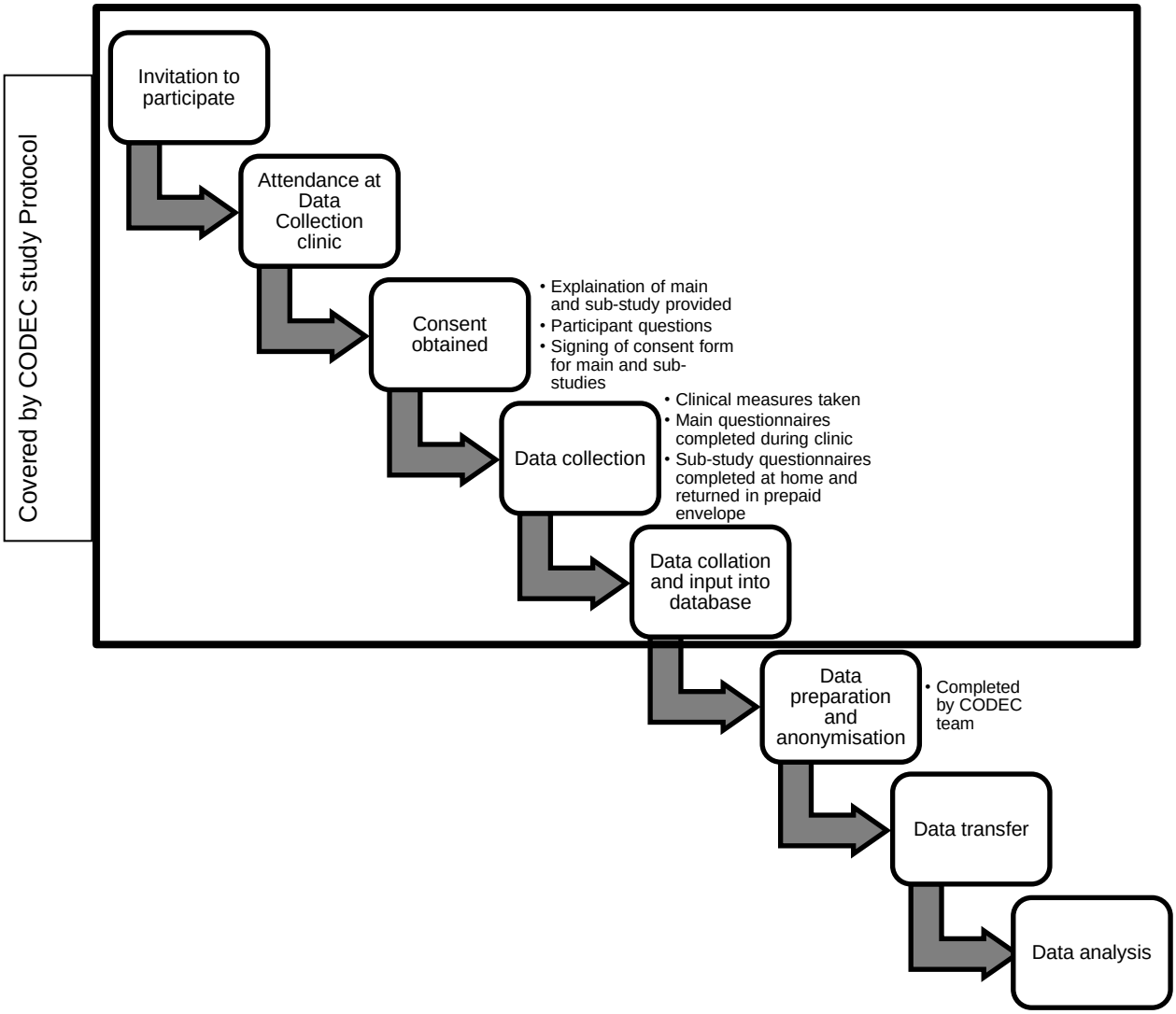
1. Participant is willing and able to give informed consent for participation in the study
2. Established T2DM (>6months since diagnosis)
3. Male or Female
4. Aged 18-75 years inclusive
5. BMI 23-45kg/m² inclusive

6. No known sleep disorders except OSA
7. HbA1c up to and below 10% (86mmol/mol)
8. On any glucose-lowering therapy or lifestyle modification for management of T2DM
9. Good command of the English language

Exclusion Criteria:

1. Participant is unwilling or unable to give informed consent
2. Anyone without a good command of the English language
3. Anyone <18 years of age and >75 years of age
4. HbA1c above 10% (86mmol/mol)
5. BMI>45 or <23 kg/m^2
6. A cannabis user
7. Have a terminal illness
8. A known sleep disorder that is not OSA
9. Taking wakefulness promoting medication i.e. Modafinil as an adjunct to the management of OSA-related sleepiness

I. Empirical Research Project Procedure Flow Chart



J. Study Approvals *

J.1. HRA approval

NHS
Health Research Authority

Mrs Sarah Henderson
[redacted]

[redacted]

02 March 2018

Dear Mrs Henderson

Letter of HRA Approval

Study title:	**The role of self-compassion in sleep and diabetes-related distress for people with type 2 diabetes**
IRAS project ID:	[redacted]
Protocol number:	
REC reference:	
Sponsor	**University of Leicester**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

Page 1 of 6

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from the HRA website.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The attached document *"After HRA Approval – guidance for sponsors and investigators"* gives detailed guidance on reporting expectations for studies with HRA Approval, including:

- Working with organisations hosting the research
- Registration of Research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found through IRAS.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details on the HRA website.

Your IRAS project ID is [redacted] Please quote this on all correspondence.

Yours sincerely

[redacted] | Senior Assessor
Health Research Authority
[redacted]
www.hra.nhs.uk

Sign up to receive our newsletter HRA Latest

Copy to: [redacted]

IRAS project ID	[redacted]

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
IRAS Application Form [IRAS_Form_[redacted]]		28 February 2018
Research protocol or project proposal	1.0	15 February 2018
Summary CV for Chief Investigator (CI)	1.0	07 February 2018

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name [redacted]

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	Consent has previously been given for anonymised data to be used in this research under the Codec study (IRAS ID[redacted]
3.1	Protocol assessment	Yes	No comments

Section	HRA Assessment Criteria	Compliant with Standards	Comments
4.1	Allocation of responsibilities and rights are agreed and documented	Not applicable	No NHS involvement
4.2	Insurance/indemnity arrangements assessed	Not applicable	No NHS involvement
4.3	Financial arrangements assessed	Not applicable	No NHS involvement
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Not Applicable	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
There is no NHS involvement for this research. HRA Approval is being given on the basis that NHS patient data is being used for this research. The Student of this educational study is undertaking all research activities. This involves the receipt of anonymised patient data and undertaking analysis.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.
As there is no NHS involvement, the study can begin according to Sponsor timelines without requiring formal confirmation of capacity and capability from the NHS.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
Not applicable

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
Not applicable

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
Not applicable

J.2. Ethics approval

UNIVERSITY OF LEICESTER

University Ethics Sub-Committee for Psychology

27/03/2018

Ethics Reference: [redacted]

TO:
Name of Researcher Applicant: Sarah Henderson
Department: Psychology
Research Project Title: The role of self-compassion in sleep and diabetes-related distress for people with type 2 diabetes

Dear Sarah Henderson,

RE: Ethics review of Research Study application

The University Ethics Sub-Committee for Psychology has reviewed and discussed the above application.

1. Ethical opinion

The Sub-Committee grants ethical approval to the above research project on the basis described in the application form and supporting documentation, subject to the conditions specified below.

2. Summary of ethics review discussion

The Committee noted the following issues:
Ethical issues are appropriately addressed to analyze a dataset from patients, which was pre-approved by the NHS REC

3. General conditions of the ethical approval

The ethics approval is subject to the following general conditions being met prior to the start of the project:

As the Principal Investigator, you are expected to deliver the research project in accordance with the University's policies and procedures, which includes the University's Research Code of Conduct and the University's Research Ethics Policy.

If relevant, management permission or approval (gate keeper role) must be obtained from host organisation prior to the start of the study at the site concerned.

4. Reporting requirements after ethical approval

You are expected to notify the Sub-Committee about:

- Significant amendments to the project
- Serious breaches of the protocol
- Annual progress reports
- Notifying the end of the study

5. Use of application information

Details from your ethics application will be stored on the University Ethics Online System. With your permission, the Sub-Committee may wish to use parts of the application in an anonymised format for training or sharing best practice. Please let me know if you do not want the application details to be used in this manner.

Best wishes for the success of this research project.

Yours sincerely,

[redacted]
Chair

J.3. Sponsor Green Light

UNIVERSITY OF LEICESTER

Research & Enterprise Division
University of Leicester
[redacted]

24 April 2018

Mrs Sarah Henderson
[redacted]

Dear Sarah

Ref: [redacted]
Study title: **The role of self-compassion in sleep and diabetes-related distress for people with type 2 diabetes**
Status: **Approved**
End Date: **30/08/2019**

I am pleased to advise you that following confirmation of a Favourable Opinion from an Ethics Committee, HRA and where relevant regulatory authority agreements have been received, the University are able to confirm sponsorship for the above research.

Please note you are required to notify the Sponsor and provide copies of:

- Changes in personnel to the Study
- Changes to the end date
- All substantial amendments and provisional and favourable opinions
- All minor amendments
- All serious adverse events (SAEs) and SUSARS
- Annual progress reports
- Annual MHRA (DSUR) safety reports (if applicable)
- End of study declaration form
- Notifications of significant breaches of Good Clinical Practices (GCP)or Protocol

If your study is adopted onto the Clinical Research Network Portfolio please ensure that your recruitment figures, end dates and study status are the same on the EDGE database and Open Database Platform (ODP) CPMS.

Please copy the Sponsor into all correspondence and emails by using [redacted]

Please note it is essential that you notify us as soon as you have recruited your first patient to the study.

I would like to wish you well with your study and if you require further information or guidance please do not hesitate to contact me.

Yours sincerely

[redacted]
Research Governance Manager

J.4. Data transfer agreement

1.0 CODEC data extraction request form

Preliminary title/area of interest: The role of self-compassion in sleep and diabetes-related distress for people with type 2 diabetes

Requester details:
Name: Sarah Henderson
Institution: University of Leicester
Email: [redacted]
Date submitted: 18/05/2018

Co-investigators of CODEC and outside study team collaborating with:

Name	Institution	Email
[redacted]		

[redacted]

Data required:

Main database & questionnaire database
Study ID
Age
Gender
Weight
BMI
Duration of diabetes
HbA1c
Diabetes related distress
Epworth sleepiness scale

From the 'wake-to-wake' activity data
Study ID
Sleep duration from the following variables
dur_nightsleep_min_pal = sleep duration (sum of all sleep episodes)
dur_night_min_pal = sleep period time window (from going to sleep to last wake up)

Social jet lag variables

midsleep_mean_we_obj = mid-sleep time weekend days
midsleep_mean_wd_obj = mid-sleep time weekdays
midsleep_mean_free_obj = mid-sleep time free days
midsleep_mean_work_obj = mid-sleep time work days
midsleep_sd_we_obj = SD of mid-sleep time weekend days
midsleep_sd_wd_obj = SD of mid-sleep time weekdays
midsleep_sd_free_obj = SD of mid-sleep time free days (hours)
midsleep_sd_work_obj = SD of mid-sleep time work days

Please note: ONLY transfer the compassion data WHEN this has been updated.

Data analysis:
Correlation analysis and hierarchical multiple regression analysis, bias-corrected bootstrapping will be conducted.

Timeframe:
May 2018 – April 2019

Do you anticipate any potential ethical concerns or conflicts of interest related to this publication?
Data protection: Anonymised data will be stored safely and securely using the University of Leicester secure network drive (R:/)

No other ethical concerns or conflicts of interest have been identified.

Any additional comments (*include any funding and stats support implications)*:

No funding has been requested for this project

Please explain what the data analysis will be contributing to (e.g. publication, education degree)

This study will be written up as part fulfilment of the requirements of a Doctorate of Clinical Psychology (DClinPsy). It is intended to be submitted for inclusion in an suitable peer-reviewed journal.

As part of a Doctorate in Clinical Psychology, this research will be recorded within the University of Leicester's School of Psychology, a summary will be made available to the public via the internet prepared by the school, and research findings may be available online via the University of Leicester Research Archive. A lay summary will also be published on the HRA's website.

Review results *(to be completed by Publication Review Committee, include any funding and stats support implications)*:
NA

This request is approved by [redacted] **This request has been completed by:** [redacted]

K. Self-report scales

K.1. Diabetes Distress Scale (DDS; Polonsky et al., 2005)

DIRECTIONS: Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 17 potential problem areas that people with diabetes may experience. Consider the degree to which each of the 17 items may have distressed or bothered you DURING THE PAST MONTH and circle the appropriate number.

Please note that we are asking you to indicate the degree to which each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would circle "1". If it is very troublesome to you, you might circle "6".

	Not a problem	**A slight problem**	**A moderate problem**	**A somewhat serious problem**	**A serious problem**	**A very serious problem**
1. Feeling that my doctor doesn't know enough about diabetes and diabetes care.	1	2	3	4	5	6
2. Feeling that diabetes is taking up too much of my mental and physical energy every day.	1	2	3	4	5	6
3. Not feeling confident in my day-to-day ability to manage diabetes.	1	2	3	4	5	6
4. Feeling angry, scared and/or depressed when I think about living with diabetes.	1	2	3	4	5	6
5. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.	1	2	3	4	5	6
6. Feeling that I am not testing my blood sugars frequently enough.	1	2	3	4	5	6
7. Feeling that I will end up with serious long-term	1	2	3	4	5	6

complications, no matter what I do.						
8. Feeling that I am often failing with my diabetes routine.	1	2	3	4	5	6
9. Feeling that friends or family are not supportive enough of self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods).	1	2	3	4	5	6
10. Feeling that diabetes controls my life.	1	2	3	4	5	6
11. Feeling that my doctor doesn't take my concerns seriously enough.	1	2	3	4	5	6
12. Feeling that I am not sticking closely enough to a good meal plan.	1	2	3	4	5	6
13. Feeling that friends or family don't appreciate how difficult living with diabetes can be.	1	2	3	4	5	6
14. Feeling overwhelmed by the demands of living with diabetes.	1	2	3	4	5	6
15. Feeling that I don't have a doctor who I can see regularly enough about my diabetes.	1	2	3	4	5	6
16. Not feeling motivated to keep up my diabetes self-management.	1	2	3	4	5	6
17. Feeling that friends or family don't give me the emotional support that I would like.	1	2	3	4	5	6

K.2. Self-compassion Scale (SCS; Neff, 2003a)

HOW I TYPICALLY ACT TOWARDS MYSELF IN DIFFICULT TIMES

Please read each statement carefully before answering. To the left of each item, indicate how often you behave in the stated manner, using the following scale:

Almost never				**Almost always**
1	**2**	**3**	**4**	**5**

1. I'm disapproving and judgmental about my own flaws and inadequacies.
2. When I'm feeling down I tend to obsess and fixate on everything that's wrong.
3. When things are going badly for me, I see the difficulties as part of life that everyone goes through.
4. When I think about my inadequacies, it tends to make me feel more separate and cut off from the rest of the world.
5. I try to be loving towards myself when I'm feeling emotional pain.
6. When I fail at something important to me I become consumed by feelings of inadequacy.
7. When I'm down and out, I remind myself that there are lots of other people in the world feeling like I am.
8. When times are really difficult, I tend to be tough on myself.
9. When something upsets me I try to keep my emotions in balance.
10. When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people.
11. I'm intolerant and impatient towards those aspects of my personality I don't like.
12. When I'm going through a very hard time, I give myself the caring and tenderness I need.
13. When I'm feeling down, I tend to feel like most other people are probably happier than I am.
14. When something painful happens I try to take a balanced view of the situation.
15. I try to see my failings as part of the human condition.
16. When I see aspects of myself that I don't like, I get down on myself.
17. When I fail at something important to me I try to keep things in perspective.
18. When I'm really struggling, I tend to feel like other people must be having an easier time of it.
19. I'm kind to myself when I'm experiencing suffering.
20. When something upsets me I get carried away with my feelings.
21. I can be a bit cold-hearted towards myself when I'm experiencing suffering.
22. When I'm feeling down I try to approach my feelings with curiosity and openness.
23. I'm tolerant of my own flaws and inadequacies.

24. When something painful happens I tend to blow the incident out of proportion.
25. When I fail at something that's important to me, I tend to feel alone in my failure.
26. I try to be understanding and patient towards those aspects of my personality I don't like.

Coding Key:
Self-Kindness Items: 5, 12, 19, 23, 26
Self-Judgment Items: 1, 8, 11, 16, 21
Common Humanity Items: 3, 7, 10, 15
Isolation Items: 4, 13, 18, 25
Mindfulness Items: 9, 14, 17, 22
Over-identified Items: 2, 6, 20, 24

Subscale scores are computed by calculating the mean of subscale item responses. To compute a total self-compassion score, reverse score the negative subscale items before calculating subscale means - self-judgment, isolation, and over-identification (i.e., 1 = 5, 2 = 4, 3 = 3. 4 = 2, 5 = 1) - then compute a grand mean of all six subscale means.

K.3. Epworth Sleepiness Scale

How likely are you to doze off or fall asleep in the situations described below, in contrast to feeling tired?

This refers to your usual way of life in recent times.
Even if you haven't done some of these things recently try to work out how they would have affected you.

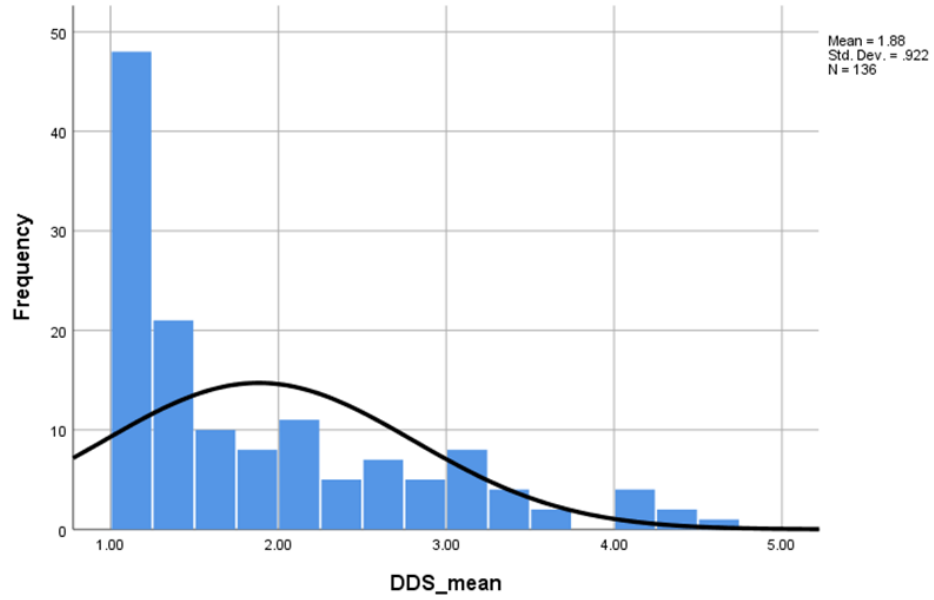
Use the following scale to choose the most appropriate number for each situation:-

0 = would never doze
1 = Slight chance of dozing
2 = Moderate chance of dozing
3 = High chance of dozing

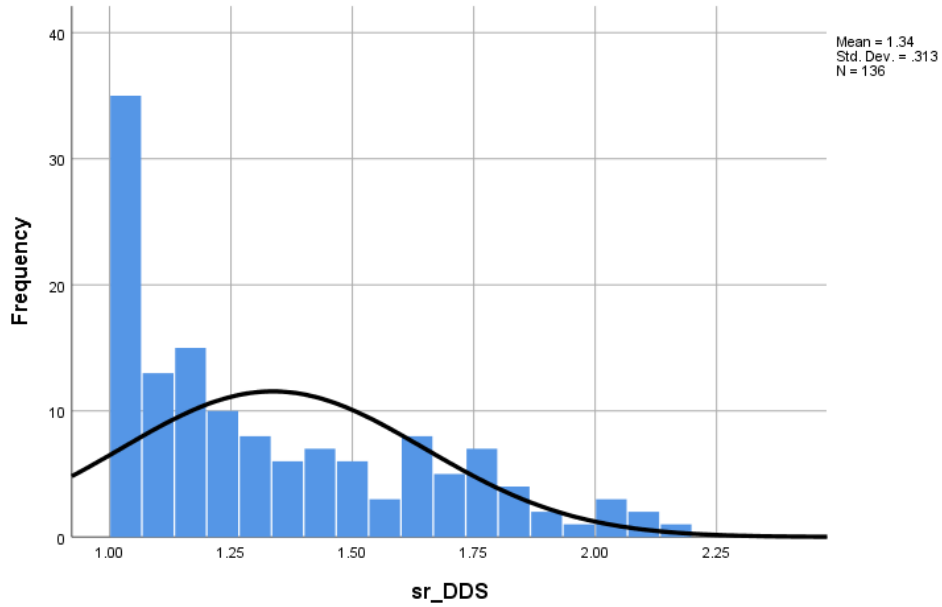
Situation Chance of dozing

1. Sitting and reading
2. Watching TV
3. Sitting, inactive in a public place (e.g. a theatre or a meeting)
4. As a passenger in a car for an hour without a break
5. Lying down to rest in the afternoon when circumstances permit
6. Sitting and talking to someone
7. Sitting quietly after a lunch without alcohol
8. In a car, while stopped for a few minutes in the traffic

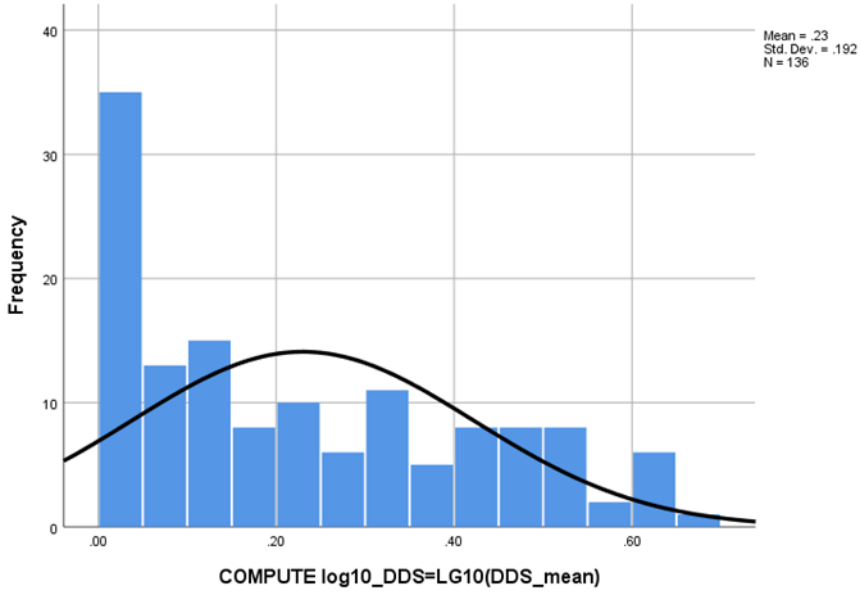
L. Example of transformation of variables



Histogram of the full scale mean Diabetes Distress Scale (DDS) for sample showing positive skew



Histogram of Diabetes Distress Scale (full scale mean) following square-root transformation which continued to show positive skew



Histogram of DDS following Log 10 transformation.

Data remains positively skewed and therefore the original DDS data was utilised with non-parametric statistical analysis, with bootstrapping.

M. Statistical analysis: Multiple Regression Analysis

The following SPSS output are included as examples of how Multiple Regression analysis was completed.

a) Example of model one: associations between diabetes related distress, daytime sleepiness and mean full scale self-compassion score

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.379[a]	.144	.117	.866	.144	5.491	4	131	.000
2	.527[b]	.277	.250	.799	.134	24.082	1	130	.000
3	.603[c]	.364	.334	.752	.087	17.568	1	129	.000
4	.605[d]	.367	.332	.753	.003	.507	1	128	.478

a. Predictors: (Constant), Diabetes_age, sr_BMI, Sex, sr_Age

b. Predictors: (Constant), Diabetes_age, sr_BMI, Sex, sr_Age, Daytime sleepiness

c. Predictors: (Constant), Diabetes_age, sr_BMI, Sex, sr_Age, Daytime sleepiness, SCS_mean_total

d. Predictors: (Constant), Diabetes_age, sr_BMI, Sex, sr_Age, Daytime sleepiness, SCS_mean_total, SCS_ESS

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	16.473	4	4.118	5.491	.000[b]
	Residual	98.251	131	.750		
	Total	114.724	135			
2	Regression	31.830	5	6.366	9.983	.000[c]
	Residual	82.895	130	.638		
	Total	114.724	135			
3	Regression	41.766	6	6.961	12.308	.000[d]
	Residual	72.959	129	.566		
	Total	114.724	135			
4	Regression	42.053	7	6.008	10.582	.000[e]
	Residual	72.671	128	.568		
	Total	114.724	135			

a. Dependent Variable: DDS_mean

b. Predictors: (Constant), Diabetes_age, sr_BMI, Sex, sr_Age

c. Predictors: (Constant), Diabetes_age, sr_BMI, Sex, sr_Age, Daytime sleepiness

d. Predictors: (Constant), Diabetes_age, sr_BMI, Sex, sr_Age, Daytime sleepiness, SCS_mean_total

e. Predictors: (Constant), Diabetes_age, sr_BMI, Sex, sr_Age, Daytime sleepiness, SCS_mean_total, SCS_ESS

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Tolerance	VIF
1	(Constant)	2.896	1.226		2.361	.020	.470	5.322		
	sr_Age	-.038	.013	-.329	-2.928	.004	-.064	-.012	.517	1.935
	Sex	.069	.159	.036	.432	.666	-.246	.384	.943	1.061
	sr_BMI	.235	.160	.123	1.469	.144	-.082	.553	.925	1.082
	Diabetes_age	.002	.010	.020	.183	.855	-.017	.021	.559	1.789
2	(Constant)	3.806	1.146		3.321	.001	1.539	6.073		
	sr_Age	-.047	.012	-.406	-3.867	.000	-.071	-.023	.505	1.979
	Sex	.064	.147	.033	.435	.664	-.227	.355	.943	1.061
	sr_BMI	-.035	.158	-.018	-.222	.824	-.347	.277	.812	1.232
	Diabetes_age	.012	.009	.140	1.361	.176	-.006	.031	.527	1.896
	Daytime sleepiness	.079	.016	.401	4.907	.000	.047	.111	.834	1.198
3	(Constant)	5.294	1.136		4.660	.000	3.047	7.542		
	sr_Age	-.041	.011	-.358	-3.599	.000	-.064	-.019	.499	2.005
	Sex	.000	.139	.000	.003	.998	-.275	.276	.932	1.074
	sr_BMI	-.097	.149	-.051	-.648	.518	-.392	.199	.804	1.244
	Diabetes_age	.013	.009	.151	1.556	.122	-.004	.030	.527	1.897
	Daytime sleepiness	.063	.016	.320	4.038	.000	.032	.094	.785	1.273
	SCS_mean_total	-.431	.103	-.322	-4.191	.000	-.635	-.228	.837	1.194
4	(Constant)	5.367	1.143		4.696	.000	3.106	7.628		
	sr_Age	-.042	.012	-.365	-3.647	.000	-.065	-.019	.493	2.027
	Sex	-.008	.140	-.004	-.056	.956	-.285	.269	.925	1.081
	sr_BMI	-.114	.151	-.060	-.750	.454	-.413	.186	.784	1.275
	Diabetes_age	.014	.009	.157	1.610	.110	-.003	.031	.523	1.912
	Daytime sleepiness	.062	.016	.316	3.964	.000	.031	.094	.781	1.281
	SCS_mean_total	-.418	.105	-.312	-3.996	.000	-.625	-.211	.812	1.232
	SCS_ESS	-.014	.020	-.053	-.712	.478	-.053	.025	.886	1.128

a. Dependent Variable: DDS_mean

Bootstrap for Coefficients

Model		Bootstrap[a]					
		B	Bias	Std. Error	Sig. (2-tailed)	BCa 95% Confidence Interval Lower	Upper
1	(Constant)	2.896	.059	1.483	.051	.070	5.990
	sr_Age	-.038	-.001	.015	.012	-.068	-.010
	Sex	.069	-.001	.159	.656	-.234	.382
	sr_BMI	.235	-.006	.178	.183	-.114	.552
	Diabetes_age	.002	.000	.010	.874	-.019	.024
2	(Constant)	3.806	-.006	1.298	.004	1.353	6.236
	sr_Age	-.047	.000	.013	.000	-.072	-.022
	Sex	.064	.005	.140	.650	-.209	.357
	sr_BMI	-.035	.000	.164	.844	-.341	.278
	Diabetes_age	.012	.000	.010	.209	-.008	.034
	Daytime sleepiness	.079	.000	.018	.000	.045	.114
3	(Constant)	5.294	-.014	1.293	.000	2.671	7.755
	sr_Age	-.041	7.189E-5	.013	.000	-.067	-.017
	Sex	.000	.005	.130	.998	-.261	.278
	sr_BMI	-.097	.002	.156	.544	-.396	.215
	Diabetes_age	.013	.000	.010	.172	-.005	.033
	Daytime sleepiness	.063	.000	.017	.001	.030	.096
	SCS_mean_total	-.431	-.001	.096	.000	-.602	-.243
4	(Constant)	5.367	-.002	1.332	.000	2.662	7.911
	sr_Age	-.042	-7.032E-5	.013	.001	-.069	-.017
	Sex	-.008	.004	.131	.947	-.271	.267
	sr_BMI	-.114	-.002	.164	.493	-.427	.206
	Diabetes_age	.014	.000	.010	.163	-.006	.035
	Daytime sleepiness	.062	-.001	.018	.001	.026	.096
	SCS_mean_total	-.418	.001	.097	.000	-.587	-.220
	SCS_ESS	-.014	-.003	.021	.484	-.058	.019

a. Unless otherwise noted, bootstrap results are based on 2000 bootstrap samples

b) Example of alternative model: associations between diabetes-related distress, daytime sleepiness, and self-compassion subscales scores.

Model Summary[d]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					
					R Square Change	F Change	df1	df2	Sig. F Change	Durbin-Watson
1	.379[a]	.144	.117	.866	.144	5.491	4	131	.000	
2	.397[b]	.157	.125	.862	.014	2.145	1	130	.145	
3	.691[c]	.478	.432	.695	.320	12.685	6	124	.000	1.763

a. Predictors: (Constant), Diabetes_age, sr_BMI, Sex, sr_Age
b. Predictors: (Constant), Diabetes_age, sr_BMI, Sex, sr_Age, duration_mean_wd_obj
c. Predictors: (Constant), Diabetes_age, sr_BMI, Sex, sr_Age, duration_mean_wd_obj, SCS_mindfulness, SCS_Self-judgement, SCS_self-kindness, SCS_isolation, SCS_common_humanity, SCS_overidentifying
d. Dependent Variable: DDS_mean

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	16.473	4	4.118	5.491	.000[b]
	Residual	98.251	131	.750		
	Total	114.724	135			
2	Regression	18.068	5	3.614	4.860	.000[c]
	Residual	96.656	130	.744		
	Total	114.724	135			
3	Regression	54.831	11	4.985	10.320	.000[d]
	Residual	59.893	124	.483		
	Total	114.724	135			

a. Dependent Variable: DDS_mean
b. Predictors: (Constant), Diabetes_age, sr_BMI, Sex, sr_Age
c. Predictors: (Constant), Diabetes_age, sr_BMI, Sex, sr_Age, duration_mean_wd_obj
d. Predictors: (Constant), Diabetes_age, sr_BMI, Sex, sr_Age, duration_mean_wd_obj, SCS_mindfulness, SCS_Self-judgement, SCS_self-kindness, SCS_issolation, SCS_common_humanity, SCS_overidentifying

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients			95.0% Confidence Interval for B		Collinearity Statistics	
		B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Tolerance	VIF
1	(Constant)	2.896	1.226		2.361	.020	.470	5.322		
	sr_Age	-.038	.013	-.329	-2.928	.004	-.064	-.012	.517	1.935
	Sex	.069	.159	.036	.432	.666	-.246	.384	.943	1.061
	sr_BMI	.235	.160	.123	1.469	.144	-.082	.553	.925	1.082
	Diabetes_age	.002	.010	.020	.183	.855	-.017	.021	.559	1.789
2	(Constant)	3.426	1.274		2.690	.008	.906	5.946		
	sr_Age	-.036	.013	-.310	-2.746	.007	-.062	-.010	.510	1.963
	Sex	.090	.159	.047	.563	.574	-.225	.405	.935	1.069
	sr_BMI	.223	.160	.117	1.395	.165	-.093	.539	.922	1.085
	Diabetes_age	.002	.010	.024	.220	.826	-.017	.021	.559	1.790
	duration_mean_wd_obj	-.001	.001	-.120	-1.465	.145	-.003	.001	.958	1.044
3	(Constant)	5.159	1.090		4.734	.000	3.002	7.316		
	sr_Age	-.025	.011	-.220	-2.386	.019	-.046	-.004	.497	2.011
	Sex	-.172	.136	-.090	-1.263	.209	-.441	.097	.834	1.199
	sr_BMI	.036	.133	.019	.269	.789	-.227	.298	.871	1.148
	Diabetes_age	.006	.008	.073	.825	.411	-.009	.022	.544	1.838
	duration_mean_wd_obj	.000	.001	-.021	-.310	.757	-.002	.001	.897	1.114
	SCS_self-kindness	.047	.092	.051	.513	.609	-.136	.230	.421	2.375
	SCS_Self-judgement	-.132	.102	-.158	-1.288	.200	-.335	.071	.281	3.556
	SCS_common_humanity	-.004	.086	-.005	-.043	.966	-.173	.166	.348	2.871
	SCS_isolation	-.162	.097	-.193	-1.667	.098	-.355	.030	.315	3.178
	SCS_mindfulness	.002	.115	.002	.017	.986	-.225	.229	.245	4.076
	SCS_overidentifying	-.279	.101	-.338	-2.770	.006	-.478	-.080	.282	3.546

a. Dependent Variable: DDS_mean

Bootstrap for Coefficients

Model		B	Bootstrap[a] Bias	Std. Error	Sig. (2-tailed)	BCa 95% Confidence Interval Lower	Upper
1	(Constant)	2.896	.024	1.442	.047	.159	5.707
	sr_Age	-.038	-.001	.014	.010	-.067	-.012
	Sex	.069	.008	.154	.663	-.254	.393
	sr_BMI	.235	-.002	.176	.193	-.096	.572
	Diabetes_age	.002	.000	.010	.854	-.018	.023
2	(Constant)	3.426	.048	1.388	.015	.708	6.311
	sr_Age	-.036	-.001	.014	.017	-.064	-.010
	Sex	.090	.009	.153	.563	-.230	.419
	sr_BMI	.223	-.002	.172	.206	-.109	.547
	Diabetes_age	.002	.000	.010	.824	-.018	.023
	duration_mean_wd_obj	-.001	-3.899E-5	.001	.182	-.004	.001
3	(Constant)	5.159	.038	1.070	.000	2.839	7.339
	sr_Age	-.025	-1.951E-6	.011	.023	-.048	-.004
	Sex	-.172	.011	.137	.214	-.450	.136
	sr_BMI	.036	-.006	.128	.789	-.211	.279
	Diabetes_age	.006	.000	.009	.457	-.011	.022
	duration_mean_wd_obj	.000	2.098E-6	.001	.750	-.002	.001
	SCS_self-kindness	.047	-.002	.087	.593	-.110	.212
	SCS_Self-judgement	-.132	.002	.108	.219	-.354	.097
	SCS_common_humanity	-.004	-.001	.081	.958	-.164	.154
	SCS_isolation	-.162	-.008	.112	.154	-.377	.029
	SCS_mindfulness	.002	.001	.108	.985	-.227	.215
	SCS_overidentifying	-.279	.007	.104	.008	-.482	-.049

a. Unless otherwise noted, bootstrap results are based on 2000 bootstrap samples

N. Statistical analysis: Mediation

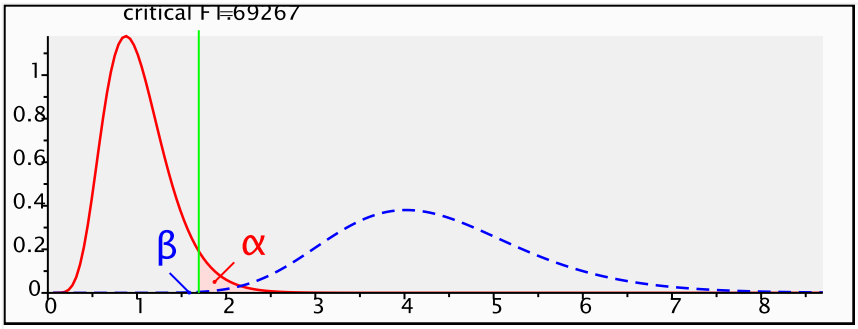
```
Run MATRIX procedure:

***************PROCESS Procedure for SPSS Version 3.00**************

          Written by Andrew F. Hayes, Ph.D.       www.afhayes.com
    Documentation available in Hayes (2018). www.guilford.com/p/hayes3

**************************************************************************
Model  : 4
    Y  : DDS_mean
    X  : SCS_mean
    M  : ESS

Sample
Size:  136

**************************************************************************
OUTCOME VARIABLE:
 ESS

Model Summary
   R       R-sq        MSE          F        df1        df2        p
.3117      .0972    19.7272    14.4211     1.0000   134.0000    .0002

Model
          coeff         se          t          p       LLCI       ULCI
constant 14.3713     1.8548     7.7483      .0000    10.7029   18.0398
SCS_mean -2.1108      .5558    -3.7975      .0002    -3.2101   -1.0114

Covariance matrix of regression parameter estimates:
          constant   SCS_mean
constant     3.4402    -1.0090
SCS_mean    -1.0090      .3089

**************************************************************************
OUTCOME VARIABLE:
 DDS_mean

Model Summary
  R       R-sq        MSE          F        df1        df2          p
.5408      .2924      .6104    27.4820     2.0000   133.0000     .0000

Model
          coeff         se          t          p       LLCI       ULCI
constant  3.0938      .3926     7.8806      .0000     2.3173    3.8703
SCS_mean  -.5023      .1029    -4.8819      .0000     -.7058    -.2988
ESS       .0574      .0152      3.7798      .0002      .0274     .0875

Covariance matrix of regression parameter estimates:
          constant   SCS_mean        ESS
constant      .1541     -.0382     -.0033
SCS_mean     -.0382      .0106      .0005
ESS          -.0033      .0005      .0002

************************TOTAL EFFECT MODEL*************************
```

```
OUTCOME VARIABLE:
 DDS_mean

Model Summary
  R       R-sq        MSE          F        df1        df2          p
.4652      .2164      .6709    37.0076     1.0000   134.0000     .0000

Model
          coeff         se          t          p       LLCI       ULCI
constant  3.9192      .3420    11.4584      .0000     3.2427     4.5957
SCS_mean  -.6236      .1025    -6.0834      .0000     -.8263     -.4208

Covariance matrix of regression parameter estimates:
          constant   SCS_mean
constant      .1170     -.0343
SCS_mean     -.0343      .0105

************TOTAL, DIRECT, AND INDIRECT EFFECTS OF X ON Y***********

Total effect of X on Y
Effect       se        t       p    LLCI     ULCI     c_ps     c_cs
-.6236     .1025    -6.0834  .0000 -.8263   -.4208  -.6764    -.4652

Direct effect of X on Y
Effect      se       t          p     LLCI     ULCI    c'_ps     c'_cs
-.5023    .1029  -4.8819     .0000   -.7058   -.2988   -.5449   -.3748

Indirect effect(s) of X on Y:
        Effect     BootSE   BootLLCI   BootULCI
ESS     -.1212      .0492     -.2328     -.0404

Partially standardized indirect effect(s) of X on Y:
        Effect     BootSE   BootLLCI   BootULCI
ESS     -.1315      .0510     -.2447     -.0461

Completely standardized indirect effect(s) of X on Y:
        Effect     BootSE   BootLLCI   BootULCI
ESS     -.0904      .0344     -.1668     -.0318

************************ANALYSIS NOTES************************

Level of confidence for all confidence intervals in output:
  95.0000

Number of bootstrap samples for percentile bootstrap confidence
intervals:
  5000
```

O. Post-hoc power calculation

F tests - Linear multiple regression: Fixed model, R^2 deviation from zero

Analysis:	Post hoc: Compute achieved power		
Input:	Effect size f^2	=	0.4310246
	α err prob	=	0.05
	Total sample size	=	136
	Number of predictors	=	18
Output:	Noncentrality parameter λ	=	58.6193456
	Critical F	=	1.6926694
	Numerator df	=	18
	Denominator df	=	117
	Power (1-β err prob)	=	0.9993291



P. Chronology of research process *

January – May 2017	Exploration of research topic through scoping searches of peer-reviewed and grey literature, and discussion with supervisors to generate ideas for research project.
March – May 2017	Development of initial research project proposal.
May 2017	Positive response from Departmental panel review regarding initial research project proposal.
June – September 2017	Continued development of research proposal. Liaison with CODEC study research team.
October 2017	Research proposal finalised and submitted for peer review.
November 2017	Feedback received from peer review approving the research project. Submission of lay summary to Service User Reference Group (SURG). Feedback received from SURG, confirming relevance for clinical population.
December 2017 – February 2018	Preparation of Research Project Protocol, IRAS form and other paperwork relating to Sponsorship, HRA and ethical approval.
February 2018	Application for University Sponsorship and HRA approval submitted.
March 2018	Application for University Ethical approval submitted. HRA approval granted.
April 2018	University Ethical approval granted.
May 2018	Sponsorship Green Light approval granted. Submission of Data Access Request to CODEC study.
June 2018	Approval of Data Access Request.
May – July 2018	Scoping searches to identify Literature Review question. Liaison with CODEC research team regarding data transfer.
July 2018	Data transfer of demographic, sleep and diabetes distress scale variables.
August 2018	Finalised Literature Review question. Development of Literature Review protocol. Data transfer of complete self-compassion variables.
August – October 2018	Systematic searches, study selection, data extraction and quality appraisal completed for literature review.
November 2018 – January 2019	Data synthesis and literature review written. Data transfer of objective sleep variables. Data analysis for empirical research.
February 2019	Preparation and submission of Literature Review to Chronobiology International.
March 2019	Finalised data analysis for empirical research.

	Writing of empirical research report. Feedback from Chronobiology International reviewers.
April 2019	Response to reviewers and revision of literature review for resubmission. Collation of appendices for thesis.
May 2019	Submission of thesis. Resubmission of literature review to Chronobiology International.
May – June 2019	Preparation and submission of empirical research to target journal.
June – July 2019	Preparation of research poster for dissemination of research at relevant conferences.
September 2019	Dissemination of research at DClinPsy Research Conference and special interest conferences.

Q. Statement of epistemological position *

A positivist approach was adopted for this project. This approach fitted with the body of research in this field identified during the literature review and which underpinned and informed the empirical research project. A positivist approach suggests that the world can be described and understood through quantitatively measured variables, and these variables can interact in ways that can be determined (Smith, 2003). Using validated measurement tools and mathematical models, relationships between these variables are established and used to understand human experiences. Variables such as mental health outcomes, diabetes-related distress, sleep characteristics and self-compassion are considered to be objective constructs that can be understood as existing because they are measurable through validated self-report questionnaires and objective measures.

The author recognises the restrictions this model presents, which is both generative and limiting within this project. Whilst the positivist model used in this work is helpful for the identification and quantification of trends across a large population, it risks losing sight of variations in experience or the influence of measures beyond the scope of this model. In particular the author considers further research is needed to investigate findings in relation to the ways in which self-perceptions and the context of living with a health condition may influence the outcomes, results and conclusions that can be made.

Reference:

Smith, J. A. (2003). Qualitative psychology: A practical guide to research methods (1st edn). London: SAGE Publications.