Running Head: MONITORING SOCIAL STIMULATION IN BIPOLAR DISORDER
Smartphone Monitoring of Social Stimulation in Bipolar Disorder: An Observational
Prospective Pilot Study
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#### **Declarations**

#### **Statement of Originality**

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. I give consent to this copy of my thesis, when deposited in the University Library\*\*, being made available for loan and photocopying subject to the Copyright Act 1968.

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### **Acknowledgement of Collaboration**

I hereby certify that the work contained in this thesis has been done in collaboration with other researchers, within a broader research project that continues to be undertaken by Dr Tanya Hanstock as part of her Doctor of Philosophy degree. I assisted in the recruitment of participants, collection of data, statistical analysis and interpretation of the data, monitored the automatic data collection, and wrote this manuscript. The project was conceived by Dr Tanya Hanstock, who, along with Prof. Frances Kay-Lambkin, designed and co-ordinated the study, supervised the implementation, recruited participants, assisted with interpretation and edited the final manuscript. Masters students, Catherine King, Madeleine Drew and Nicole Carter, also contributed to the research design and implementation, and contributed to the data collection and recruitment of participants, along with Gabriel Heaton, Charlotte Jones, Renee Morrison. Each student's thesis focusses on a different area or timeframe and separate data analyses are being completed for each study. Prof. Simon Dennis assisted with the methodology and provided technical assistance, along with Andrew Hide and Ben Stone. Paul Rippon conducted the statistical analysis and assisted with data interpretation.

# **Statement of Authorship**

I hereby certify that the work embodied in this thesis contains a scholarly work of which I am a joint author. I have included as part of the thesis a written statement, endorsed by my supervisor, attesting to my contribution to the joint scholarly work.

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# **Formatting Style Used in This Thesis**

This thesis is formatted according to the *Publication Manual of the American*Psychological Association, sixth edition. The manuscript was formatted for submission to the Journal of Affective Disorders, in line with the submission guidelines and instructions for authors which are contained in Appendix A.

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Smartphone Monitoring of Social Stimulation in Bipolar Disorder: An Observational

Prospective Pilot Study

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#### **Abstract**

*Background*: Social stimulation is the internalised response to social interactions. Irregularity in social stimulation is associated with relapse in Bipolar Disorder (BD) and may represent early-warning signs. Smartphones have the capacity to objectively monitor social stimulation by automatically sensing relevant data, such as telecommunications. This study explores the tolerability of long-term, objective monitoring of social stimulation in BD, using Android smartphones, and participants' mood over time.

*Methods*: We recruited a small sample (*n*=12) of individuals with BD for prospective observation of social stimulation and mood. The Berk Depression Rating Scale, Young Mania Rating Scale and Duke Social Support Inventory were administered at baseline, 1-week, 3-, 6-, 9- and 12-months. Phone call and SMS logs, collected via Unforgettable Me and If This Then That applications for up to 12-months, were summarised by day.

Results: Individual cumulative sum charts facilitated identification of change in telecommunication patterns and exploration of correspondence between these change points, mood and social stimulation measures. Technological difficulties impacted the tolerability of long-term monitoring.

Limitations: The small, mainly female sample, restricted smartphone operating system and inability to capture social-media messaging were the main limitations of this study.

Conclusions: This research highlights the opportunities and challenges of automated monitoring of social stimulation in BD, adding to the evidence that subject-specific behaviour patterns offer important insight into mood state in BD. Ongoing efforts to establish reliable data collection, along with more sophisticated change point detection methods, is needed to enhance monitoring of early-warning signs to prevent relapse in individual's with BD.

Keywords: Bipolar Disorder, Social Stimulation, Depression, Mania, Smartphone, Monitoring

### **Highlights**

- Social stimulation irregularity is an early warning sign in Bipolar Disorder (BD).
- Telecommunications may be a useful indicator of changes in social stimulation.
- Technological reliability impacted long-term, objective monitoring tolerability.
- Changes in telecommunication corresponded to BD symptoms for some participants.
- Change point detection has promise for investigating behavioural time series data.

Smartphone Monitoring of Social Stimulation in Bipolar Disorder: An Observational

Prospective Pilot Study

Bipolar Disorder (BD) is a severe, recurrent mood disorder, yielding significant burden of disease (World Health Organisation, 2008) and high risk of suicide (American Psychiatric Association [APA], 2013; Pallaskorpi et.al., 2017; Saunders & Hawton, 2015). The ability to predict relapse is an important but challenging goal. The bipolarity of mood symptoms and idiosyncrasy of early-warning signs make it difficult to identify early shifts in trajectory. Predicting relapse in BD is also subject to insight, recollection and medication adherence (Malhi et al., 2015; Miklowitz, 2014), which are influenced by symptoms of BD (Goodwin & Jamison, 2007; Murnane et.al., 2016).

Self-monitoring is the current mainstay of symptom monitoring in BD. Evidence about the ability of individuals with BD to accurately self-identify early-warning signs is mixed (Goossens et.al., 2010; Lam & Jones, 2006). However, self-monitoring has the potential to raise awareness of early-warning signs by increasing insight, autonomy and engagement in treatment (Faurholt-Jepsen, Munkholm et.al., 2016; Lam & Jones, 2006). A recent trend towards technological monitoring methods has been noted (Murnane et.al., 2016), including smartphone applications (apps) for symptom monitoring (Nicholas et.al., 2017). However, few of the monitoring apps currently marketed for use in BD are evidence-based.

Social stimulation, a known correlate of mood instability in BD (Ehlers et.al, 1988; Frank, 2005), is an internalised response to social interactions and activities, including conversations, events, phone calls, messages, social-media and work/leisure routines. Levels of social stimulation have the potential to influence and be influenced by BD symptoms, including psychomotor agitation and retardation, pressured speech, diminished interests and increased goal-directed activity (APA, 2013). In maintaining stable mood, it is beneficial for routines to provide enough social stimulation, preventing depression, without being over-

stimulating, thus contributing to hypomania and mania (Frank et.al., 1997).

As social stimulation early-warning signs are increasingly understood, clinical attention is shifting towards effective ways of monitoring social stimulation. Until recently, self-report monitoring of social stimulation was only undertaken within therapeutic interventions, such as the Social Rhythm Metric (Frank, 2007) in Interpersonal and Social Rhythm Therapy (Frank, 2005). While not overlooking the benefits of self-monitoring, objective data has the potential to add significantly to the clinical picture (Matthews et.al., 2016). The evolution of 'lifelogging', automated recording and storage of information relating to daily activities, and advances offered by the smartphone revolution means remote, passive monitoring is increasingly available, cost-effective and non-invasive (Harari et.al., 2016).

The average smartphone has in-built sensing capacity for a range of human behaviours (Lane et.al., 2014), with an increasing number of downloadable apps to passively collect this data. Many characteristics of social stimulation, such as phone calls, messaging, conversations and geographical movement, lend themselves to this type of objective sensing and quantification (Harari et.al., 2016). Therefore, remote monitoring offers a unique opportunity for automatic detection of social stimulation early-warning signs, and potential activation of early intervention to prevent relapse (Faurholt-Jepsen et.al., 2018), providing the prediction algorithms are sensitive and specific enough. Researchers have begun to explore this potential, focussing on telecommunication markers of social stimulation. Significant associations between phone call and short message service (SMS) and mood have been found (Beiwinkel et.al., 2016; Faurholt-Jepsen et.al., 2015; Faurholt-Jepsen, Vinberg et.al., 2016).

A group of Danish researchers demonstrated the potential for telecommunication patterns to correspond to BD mood state, with their *Mon*itoring, Treatment and Prediction of Bipolar Disorder Episodes (MONARCA) app. In initial research with 61 individuals with BD receiving long-term treatment at a specialised out-patient clinic, over 6-months, Faurholt-

Jepsen et.al., (2015) reported objective, automatically-sensed telecommunications data could differentiate between mood states. They found positive correlations between the duration of received phone calls and both mania and depression, while increased duration of placed calls and increased frequency of placed calls, received calls and SMS sent correlated with mania symptoms. However, the ability to generalise these results to BD populations in the broader community is limited by the exclusion of individuals who were clinically symptomatic at baseline and provision of new, standardised smartphones.

Further evaluation of the MONARCA app with 29 more severely symptomatic BD out-patients, found a positive correlation between depressive symptomology and received calls and missed calls, and a negative relationship with placed calls per day (Faurholt-Jepsen, Vinberg et.al., 2016). Additionally, manic symptomology correlated positively with the frequency of SMS sent and the duration of received calls, and negatively with the duration of placed calls and number of characters in received SMS. Despite potential limitations of sample size and 3-month timeframe, Faurholt-Jepsen, Vinberg et.al. (2016) reported objective telecommunications data has efficacy in reflecting the level of affective state in BD.

Longer-term monitoring of telecommunications, using the Social Information Monitoring for patients with Bipolar Affective Disorder (SIMBA) app, has also showed promise as an effective adjunct to routine care for BD (Beiwinkel et al., 2016). Monitoring 13 individuals with BD, who were out-patients of a German psychiatric clinic, for 12-months, this study reported automatically sensed telecommunication patterns could predict manic and depressive relapse. Specifically, the number of calls placed predicted increased manic symptomology and the number of SMS sent predicted increased depressive symptomology. However, the small sample, limited variability in mood and provision of new, standardised smartphones, represent limitations to these findings.

So far, smartphone technologies have shown promise for automatically sensing

telecommunications which correlate with BD mood state (Beiwinkel et.al., 2016; Faurholt-Jepsen, Vinberg et.al., 2016; Frost et.al., 2013; Grünerbl et.al., 2015). Individual (rather than normative) behavioural comparisons have been implicated in accurate detection of objective early-warning signs (Muaremi et.al., 2014; Osmani et.al., 2013), reflecting current clinical practices (National Collaborating Centre for Mental Health, 2018). Further investigation of idiosyncratic social stimulation characteristics in BD is required in order to generalise these results more broadly.

Existing research has relied on specifically-designed apps and new, standardised smartphones, increasing costs and impairing the generalisability of these results to real-world applications. Meanwhile, an abundance of generic, commercially-available apps are able to record numerous lifestyle behaviours from an individual's existing smartphone, providing an economical alternative (Jake-Schoffman et.al., 2017). While increasing ecological validity, tolerability and adherence (Harari et.al., 2016), these methods are unobtrusive and may protect the user from potential stigma of specific monitoring technologies (Bauer et.al., 2017; Matthews et.al., 2016). However, these apps are largely untested in BD.

The current study presents an exploratory investigation into the validity of objective monitoring of social stimulation in BD, using existing smartphones, and the relationship with mood over time. The research questions for this study are: is long term assessment and monitoring of social stimulation and mood symptoms tolerable for individuals with BD across a 12-month period? Are objective measures of telecommunications a valid indicator of social stimulation in BD? Are changes in objective measures of telecommunication associated with changes in depression and/or mania?

### 2. Methods

### 2.1 Ethical Approval

Ethical approval was gained from the Human Research Ethics Committees of the

University of Newcastle (UON; approval number H-2016-0067; Appendices B-C) and Hunter New England Local Health District (HNELHD; reference number 16/03/16/4.05; Appendices D-E).

### 2.2 Participants

Participants were community volunteers, who self-referred in response to advertising (Appendix F) displayed at UON Callaghan and Ourimbah campuses, private psychology/ psychiatry practices in the Newcastle region and HNELHD Mental Health Services. Inclusion criteria required participants to be aged 18-50 years, with existing diagnosis of BDI or BDII, under the care of a General Practitioner (GP), Psychologist or Psychiatrist, native English speakers and have an Android smartphone. Individuals who were acutely unwell, had a serious medical condition, brain injury, learning disorder or intellectual impairment were excluded. Participants were compensated with a \$10 gift card per hour of clinical assessment (to a maximum of \$100).

#### 2.3 Materials

### 2.3.1. Structured Clinical Interview for DSM-5 Disorders – Research Version (SCID5-RV)

Participants' diagnosis of BDI or BDII was confirmed using Module A of the SCID5-RV (First et.al., 2015), a semi-structured clinical interview of mood symptomology aligned with the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (APA, 2013). Previous versions of the SCID have good validity (Fennig et.al., 1994) and inter-rater reliability ( $\kappa$  =.71) (Lobbestael et.al., 2011).

### 2.3.2. The Bipolar Depression Rating Scale (BDRS)

The BDRS (Berk et al., 2007) is a 20-item clinician-rated measure of depressive symptomology in individuals with BD, within the preceding 48-hours (Appendix G). Symptoms are rated on a 4-point scale, from 0 (absent) to 3 (severe) yielding a maximum score of 60. Subsyndromal depression is determined by a score of 9 or more, while clinical

depression is attributed to scores above 16 (Tohen et.al., 2009). Research has demonstrated good validity and robust internal reliability (Cronbach's  $\alpha$  = .92; Berk et al., 2007), a finding supported at baseline in the current study ( $\alpha$ = .95).

### 2.3.3. Young Mania Rating Scale (YMRS)

The YMRS (Young et.al., 1978) is an 11-item clinician-rated assessment of the severity of (hypo)manic symptomology in individuals with BD, across the preceding 48-hours (Appendix H). Symptoms are rated on a 5-point scale, from 0 (absent) to 4 (severe) with a maximum score of 60. Hypomania is determined by a score of 8 or more, while mania is attributed to scores above 14 (Tohen, et.al., 2009). The YMRS has excellent inter-rater reliability ( $\kappa$ = .93; Young et.al., 1978) and good internal consistency ( $\alpha$ = .81, Leidy et.al., 1998), a finding replicated at baseline in the current study ( $\alpha$ = .75)

### 2.3.4. Duke Social Support Index (DSSI)

The DSSI (Wardian et.al., 2012), a 10-item self-report measure of social support and interaction across the previous 7-days (Appendix I), is one of few validated measures for the general population. Items require frequency or a rating of hardly ever/some of the time/most of the time, scored to a maximum of 30, with higher scores indicate more interaction and support. The DSSI has acceptable reliability ( $\alpha$ = .74; Wardian et.al., 2012), which was replicated at baseline in the current study ( $\alpha$ = .80).

#### 2.3.5. Telecommunications

Phone call and SMS logs from each participant's smartphone were automatically collected by If This, Then That (IFTTT), a free, conditional activity app which integrates smartphone and web-based apps, and recorded by Unforgettable.me (UM; in-beta 2016/2017), a lifelogging app for Android operating systems (Hamm et.al., 2012). The apps were chosen in collaboration with other researchers at the University of Newcastle due to commercial availability, no cost and access to technological support. Frequency and duration data

automatically uploaded from the UM app to a secure website, monitored by the researchers, when the smartphone had internet connection (WiFi) and was charging, with battery greater than 90%.

Participant privacy was protected throughout the study using randomly generated participant ID's and use of generic email addresses for registration with third party services, which limited the personal information provided to these services. Privacy was also protected using obfuscated phone numbers with consistent coding to facilitate a unique identifier for each contact. Obfuscated numbers with fewer than 5 digits, were likely to represent automated services rather than social communications and were removed from the data set.

#### 2.4 Procedure

Participants attended a baseline assessment with a Clinical or Provisional Psychologist at a University Psychology Clinic, where they reviewed the Participant Information Sheet (Appendix J) before providing informed consent (Appendix K). Personal and demographic data were collected (Appendix L) before the SCID5-RV, BDRS, YMRS and DSSI were administered. UM and IFTTT smartphone apps were installed on the participant's personal Android smartphone, and automated telecommunications data collection was initiated.

The BDRS, YMRS and DSSI were readministered at each subsequent assessment, occurring at 1-week, 3-, 6-, 9- and 12-months. Semi-structured interviewing was then undertaken to elicit a short narrative of the course of the participants BD during the intervening period (Appendix M). Following each assessment, researchers liaised with the participant's Treating Professional/s, reporting on current mood state and collaboratively managing risk (where required). Objective data, from the secure website, was reviewed by the researchers on a weekly basis to manage any technical issues.

#### 2.5 Data Analysis

The current study involved prospective observation over a 12-month period within a

naturalistic setting. Analyses were conducted using the R statistical computing program (R Core Team, 2018). Previous research undertaken by our team, utilising Linear Mixed Effect Modelling across the cohort, identified idiosyncratic telecommunications patterns and missing data limited the utility of cohort analysis within the current data set (Carter et.al., 2017), suggesting the need for within-subject analyses in the current research.

Although the sample was small, the analytic approach needed to condense the thousands of sequential data points generated by passive monitoring into a digestible, credible format. It also needed to account for within-subject dependence and large portions of missing data which meant data was not necessarily sequential in time. An additional challenge was the lack of predetermined parameters for what constituted significant change in telecommunications. Idiosyncratic behaviours mean patterns of telecommunications vary greatly between individuals, both in normal patterns of use as well as during periods of depression and (hypo)mania. Rather than identifying periods of mood instability from which to evaluate telecommunications, we employed a bottom-up approach which attempted to identify data-driven changes in telecommunications behaviour from which to explore mood symptoms.

Change point (CP) detection methods were used to identify changes within each participants telecommunications data over time, independent of a priori definitions (Aminikhanghahi & Cook, 2017). The frequency and duration of phone calls, and frequency of SMS data, were firstly summarised into daily totals. Cumulative sum (CUSUM) charts were used to identify potential change points in each variable of interest (Duration of Calls Placed, Duration of Calls Received, Calls Placed, Calls Received, Calls Missed, SMS Sent and SMS Received) for each subject.

$$Q_i = \sum_{i=1}^i (y_j - \bar{y})$$

Individual daily data,  $\mathcal{Y}_i$ , was compared to the mean of the longitudinal data set,  $\bar{\mathcal{Y}}$ , with the difference summed cumulatively to generate the CUSUM,  $\mathcal{Q}_i$ , for the data up to day i. Broad changes in the slope of the CUSUM are indicative of the presence of a change point, indicating a change in the pattern of an individuals' telecommunications.

To manage the large amounts of missing data, complete data sets were generated using a linear interpolation between the data points either side of the missing period. This was a pragmatic choice to facilitate the analyses. CPs were identified visually, by multiple rater review of change in slope in the CUSUM charts. The location of the missing data was highlighted across all graphs and raters discounted the credibility of potential CP around large, or regular, periods of missing data. We then explored the clinical mood data and corresponding contextual data at that time period for each subject (see Appendices N-P), where correspondence was indicated by proximity of events within 14 days.

Due to the potential for longitudinal human behavioural data to be impacted by events, such as work/leisure patterns, that might influence change in behaviour patterns that are unrelated to mood state, a rolling 7-day mean was used to smooth the data and reduce noise in the CUSUM output. The data analysis procedure was exploratory in nature, describing, rather than testing the significance of, trends in peaks and troughs of the social stimulation data relative to peaks and troughs in standardised symptom measures.

### 3. Results

#### 3.1 Sample

Twelve participants (10 females, 2 males), aged 23-50 years (M = 33.5 years, SD = 8.2) with BDI (n = 5) and BDII (n = 7), were recruited to the study as they self-referred between November, 2016 and May, 2017. Participant baseline socio-demographic characteristics are presented in Table 1. Of these, six participants completed the 12-month assessment and monitoring period. Two participants formally withdrew prior to 3-month

assessment, while one participant withdrew prior to 6-month assessment. Additionally, 3 participants were lost to follow-up, prior to 9-month assessment (n= 1) and 12-month assessment (n=2). All participant data were retained for analysis, with permission. Participants who did not provide telecommunications data (n= 1), or had regular periods of missing telecommunications data (n= 1), were excluded from the analyses, leaving a sample of 10 participants for analysis.

### 3.2 The Tolerability of Long-term Assessment and Monitoring in BD

Tolerability was operationalised into duration of participation, compliance with clinical assessments, and provision of objective telecommunications data throughout the 12-month study period (see Table 2). For the analysed sample (n= 10), mean duration of participation was 330.9 days, ranging from 183 to 377 days. Clinical assessment data was collected on 49 out of 60 possible occasions (81.7%). For participants who disengaged from clinical assessment or withdrew from the study, associated contextual factors included interpersonal loss (8.3%), interstate/international relocation (16.6%) and medication cessation (8.3%). Objective telecommunications data was logged on a total of 2409 days (M= 240.9, SD= 69.2), out of a total of 3309 days participants remained in the study (72.9%). Self-report during clinical assessment identified none of the 10 participants reviewed their smartphone data on a regular basis (0%).

### 3.3 Telecommunications as an Indicator of Social Stimulation

Social stimulation was operationalised as participant scores on the DSSI, with higher scores indicating greater social stimulation. Mean DSSI scores for the analysed sample remained relatively stable over time (M= 22, SD= 1.09; see Table 3), with limited intraindividual variation (SD ranging from 0.0 - 5.0, M= 2.4; See Table 3).

### 3.3.1 Correspondence between Telecommunications CP and lower DSSI scores

For 5 of 10 participants, lower DSSI scores corresponded with CPs in objective telecommunication data. For an example, see Participant 3's DSSI score of 19 at 3-month assessment, corresponding to CPs in Duration of Calls Placed, Duration of Calls Received and Calls Placed at 18/19<sup>th</sup> March (Figure 1, note a). These CPs indicated a transition from decreased frequency and duration to increased telecommunications. This DSSI score is the lowest recorded score for this participant (M= 21.7, SD= 1.8). Clinical contextual information (see Appendix P) from this period indicated this participant had been experiencing interpersonal work-related stress leading to a change in occupation, and marital discord resulting in relationship counselling, leading up to this assessment point.

3.3.2 Correspondence between Telecommunications CP and higher DSSI scores

For 1 of these participants, higher DSSI scores also corresponded with a CP in objective telecommunication data. Participant 5 provides an example of this (See Figure 1, note b) where their highest DSSI score of 27 at 6-month assessment corresponded to CPs in Duration of Calls Placed, Calls Placed, Calls Received, Calls Missed and SMS Sent at  $14-17^{th}$  June, marking a transition to decreased duration and frequency. In correspondence, clinical contextual information (see Appendix P) indicated this participant had been seeking social stimulation and more socially active to this assessment time-point, prior to a physical injury which corresponded to the CP. For the remaining 5 participants, no discernible trend was identified, either because few CPs were detected (n=1), few DSSI scores were recorded (n=1) or DSSI scores showed little variability (n=3).

3.4 Correspondence Between Change in Telecommunication and Mood Symptoms

Clinical threshold for depression was met on 30.6% of occasions, and a further 42.7% met threshold for subsyndromal depression (see Table 3). All participants scored above the BDRS clinical threshold at least once during the study period, while 40% of participants had a mean BDRS score above the clinical threshold throughout (see Table 3). In contrast, mania

was rare with only 6 YMRS scores (12.2%) exceeding the clinical threshold across the study duration (see Table 3). On 4 of these occasions (8.1%), the BDRS threshold also met. Hypomania was identified by the YMRS on an additional 11 occasions (22.4%), with each of these also corresponding to clinical or subclinical BDRS scores (see Table 3).

3.4.1 Correspondence between Telecommunications CP and lower BDRS scores

For 3 out of 10 participants, lower BDRS scores corresponded to a CP in objective telecommunications data. In this example (see Figure 2, note a) Participant 5's BDRS score of 4 corresponds to CPs marking an increase in Duration of Calls Placed, SMS Sent and SMS Received. Corresponding clinical contextual information (see Appendix P) from this period indicated this participant was emerging from a period of chronic dysthymia, associated with major interpersonal stressors, into a mildly elevated mood state since a change in medication 2 weeks prior to the CP.

3.4.2 Correspondence between Telecommunications CP and higher BDRS scores

This same participant's higher levels of depression (BDRS score of 12) at 6-month assessment, corresponded to CPs in Duration of Placed Calls, Calls Placed, Calls Received, Calls Missed, SMS Sent and SMS Received at 14-17<sup>th</sup> June (See Figure 2, note b). This marked a transition to decreased frequency and duration of telecommunications. Clinical contextual information (see Appendix P) indicated, during this period, the participant incurred an injury which resulted in reduced physical activity and lower mood. Six out of 10 participants also recorded increased BDRS scores (subsyndromal or clinical) and concomitant CPs in objective telecommunications data. For the remaining participants, no discernible correspondence with BDRS score was identified, either because few CPs were detected (*n*=1), both BDRS and YMRS scores were elevated (n=2) or few BDRS scores were recorded (*n*=1).

For 6 of 10 participants, low YMRS scores corresponded with CP in objective

telecommunications data. Of note, low YMRS scores were accompanied by increased BDRS scores on 5 of these 6 occasions. See Figure 3, note a, for an example, where Participant 3's YMRS score of 5 and BDRS score of 19 at 6-month assessment, corresponded to CPs in Duration of Calls Placed, Duration of Calls Received, Calls Placed, Calls Received and Calls Missed at 18/19<sup>th</sup> March, marking increased frequency and duration of telecommunications. Clinical contextual information (see Appendix P) from this period indicated this participant had been experiencing consistent mild depression throughout the preceding period, along with wide-ranging interpersonal stresses and change in employment leading up to this assessment point. For the remaining 3 participants, no discernible correspondence with YMRS score was identified, either because few CPs were detected (*n*=2), few YMRS scores were recorded (*n*=1) and YMRS scores showed little variability (*n*=3).

3.4.4 Correspondence between Telecommunications CP and higher BDRS and YMRS scores

For 3 out of 10 participants, higher scores on both the BDRS and YMRS (subsyndromal or clinical) corresponded to a CP in objective telecommunications data. Figure 3, note b, provides an example of this, where Participant 4's 1-week assessment YMRS score of 22 and BDRS score of 15 correspond to a CP in Calls Placed, marking a transition into more stable frequency. Clinical contextual information (see Appendix P) from this period, immediately preceding Christmas, indicates elevated mood across the preceding week was attributed to a medication change, where this participant was more motivated to socialise, evolved into a period of euthymic mood in the period immediately after. No discernible trend relating to high scores on both mood measures was noted for the remaining 6 participants, either due to too few periods of dual high scores (n=4), few mood scores recorded (n=1) or few CPs detected (n=2).

### 4. Discussion

This study investigated a novel approach to identifying change in objective social

stimulation variables which are associated with mood instability in BD. The research aimed to explore the tolerability and validity of long-term objective monitoring of social stimulation in BD, and the relationship to mood over time.

### 4.1 The Tolerability of Long-term Assessment and Monitoring in BD

This study demonstrated a level of non-compliance with the long-term assessment and monitoring schedule. This is not unusual in long-term studies of this nature, with Beiwinkel et.al. (2016) reporting 72.1% compliance with scheduled assessment and provision of social data on 56.1% of expected occasions in their 12-month study of objective monitoring in BD. Additionally, previous research into the use of smartphone apps to monitor symptoms in BD has reported increased attrition over time (Hidalgo-Mazzei et.al., 2016). Thus, to maximise the potential of objective monitoring in BD in the future, identifying strategies to sustain uptake and use of these technologies over the longer term will be beneficial (Batra et.al, 2017).

Within this study, a number of technological issues affected the automaticity and reliability of the smartphone data, including limited access to reliable WiFi, competing software updates and other glitches which resulted in the apps being switched off or not recording without the participant's knowledge. The sampling requirements of UM also appear to have negatively impacted the battery life of older smartphones, which may have decreased the availability of the data and participant compliance (Harari et.al., 2016). These issues required collaborative troubleshooting with the participant, either via phone/email or during in-person appointments. Anecdotally, participant burden increased due to the regularity of technology issues, with one participant reporting setting a reminder to check the app was functioning. Another participant reported needing to carry an external battery pack due to increased battery drain. Of interest, neither of these participants completed the full period of assessment and monitoring. Overall, efforts to remediate technical issues are likely to have

impacted the tolerability of this type of monitoring and contributed to attrition.

Clinical interviewing generally identified participants were not using the UM and IFTTT apps, other than to troubleshoot malfunctions as per instructions. Although no specific detail about why there were not engaging with the app were provided, it may be that the interface was not intuitive, did not provide the information in a useable format or they perceived the data did not have relevance for them. While there was no feedback from participants about privacy concerns, it may be that the use of third-party apps impacted participant's willingness to engage more fully with the apps. Overall, despite the economic benefits of commercially-available apps, accessibility and functionality issues limits the useability of these in their current form. User-centred interfaces, developed alongside consumers and clinicians to meet the needs of individuals with BD, demonstrate higher levels of user satisfaction (Hidalgo-Mezzei et.al., 2016), therefore user feedback and field testing of the apps used in this study may be useful in ongoing app development (Jake-Schoffman et.al., 2017). Increasing the automaticity and reliability of the technology, along with relevant and informative output, will also enhance future research.

#### 4.2 Telecommunications as an Indicator of Social Stimulation

In this study, the DSSI served as a broad proxy for social stimulation against which telecommunications usage patterns were compared. Intra-individual variability in DSSI scores was limited in the current sample (See Table 3). When combined with objective data featuring large amounts of missing data, our ability to draw definitive conclusions about the efficacy of telecommunications as an indicator of social stimulation in this sample was limited. However, trends in correspondence between telecommunications and DSSI scores were noted for some participants. Specifically, a pattern of lower DSSI scores (low social stimulation) was associated with CPs indicating an increase in participant-initiated communications (e.g. Calls Placed, SMS Placed) and stability in communications initiated by others (e.g. Calls Received,

Calls Missed and SMS Received). Thus, for these participants, actively contacting others was associated with lower self-reported social stimulation and may represent attempts to access additional social support during times of under-stimulation. No consistent trend in mood was identified to correspond with this pattern, with increased depression and hypomania noted for different participants at these time-points.

In contrast to literature indicating higher levels of social stimulation would correspond with higher levels of telecommunications, particularly in participant-initiated calls and SMS (Beiwinkel et.al., 2016; Faurholt-Jepsen, Vinberg et.al., 2016), this trend was only identified for one participant's CP. Conversely, higher levels of social stimulation corresponded to a CP indicating a decrease in telecommunications in another participant. This idiosyncrasy is expected given the established heterogeneity between individuals with BD, and represents the inherent difficulty with identifying cohort trends of behavioural markers of social stimulation.

4.3 Correspondence Between Change in Telecommunication and Mood Symptoms

Depression, rather than mania, was the predominate mood state in this study. While more than 70% of BDRS scores indicated subthreshold or clinical depression across the monitoring period, less than 35% of participant scores on the YMRS exceeded the threshold for mania or hypomania. Where mania or hypomania was indicated by YMRS scores, these were accompanied by elevated BDRS scores indicating a mixed-mood state. This reduced our capacity to draw conclusions about the relationship between changes in social stimulation and elevated mood. However, CPs in telecommunications marking transitions between periods of use which were higher or lower than average did correspond to changes in mood state at some time-points, for some participants. Overall, these trends were idiosyncratic and not definitively mood congruent.

Increased written output can be an indicator of psychomotor agitation, flight of ideas and pressured speech in a manic mood episode (APA, 2013). As the 'SMS language' lends

itself to rapid typing, using standard acronyms, truncations and expressive graphics, the frequency and content of SMS sent may represent observable indictors of manic symptoms. Given this, previous findings associating increased frequency of SMS Sent correlated with manic mood (Faurholt-Jepsen et.al., 2015; Faurholt-Jepsen, Vinberg et.al., 2016) and predicted lower levels of depression (Beiwinkel et.al., 2016) are unsurprising. In our study, changes in SMS Sent behaviours, indicating either stability or reduced frequency, corresponded with lower YMRS scores. On all but one of these occasions, the participant's BDRS scores increased at the same time, perhaps indicating these changes in SMS Sent behaviour are a function of psychomotor activity transitioning between mood states. As there were no CP in SMS Sent which corresponded to a period of mania, we are unable to draw conclusions about the correspondence of increased SMS Sent and mania in this cohort.

Despite the evidence of a relationship between telecommunications and mood in the existing research, no evaluation of the impact of socio-economic factors has been undertaken. Phone plans (which include financial limits for placed calls and SMS's) have the potential to drive telecommunication behaviour, meaning changes in an individual's telecommunications may be driven by underlying financial constraints rather than mood state changes. In this study, one participant demonstrated very few Calls Placed, and consistently lower Duration of Placed Calls, when compared to the frequency and duration of Calls Received. It may be hypothesised that, for this participant, patterns of telecommunications may be influenced by the costs of these contact, resulting in shorter placed calls and requests for others to call them. Future research investigating naturalistic telecommunications should include an evaluation of broader factors which may influence telecommunications behaviours.

Combining sensor data, such as integrating SMS data or weighting call frequency and duration data to create overall call variables, may prove useful in increasing the clarity of CP and facilitating better identification of change. In this research, associations between the trend

of SMS Sent and SMS Received, and between the type of Call (Placed or Received) and the Duration of Call (Placed or Received), were noted on many occasions, however there were equally times when a change in one was not reflected in the other. Additionally, correspondence in CPs for Calls Missed and Calls Placed, which may be hypothesised as calls made in response to unanswered contact from others, occurred frequently but not consistently.

Within the MONARCA project, attempts to achieve an amalgamated social activity measure, combining all objective call and SMS data, have had some success (Frost et.al., 2013; Grünerbl et.al., 2014). However, this 'all-in' approach runs the risk of overlooking specific nuances of incoming and outgoing communication behaviours which have shown promise in discriminating between the polarities of BD mood (Beiwinkel et.al., 2016; Faurholt-Jepsen et.al., 2014; Faurholt-Jepsen, Vinberg et.al., 2016). Therefore, more research is needed to clarify which, if any, amalgamated telecommunications measures add clarity to exploration of mood state, without reducing specificity.

Finally, it is important to consider that any changes detected may actually be associated with or influenced by an alternative variable rather than reflecting underlying change in social stimulation. Clinical contextual information gathered during the study period indicated the presence of a number of psychosocial stressors, including job loss, separation/divorce, relocation, pregnancy and grief, that could account for changes in the participant's telecommunication patterns and would be likely to affect mood states.

### 4.4 Strengths

This research is the first to use an Australian, community-based sample, using existing, familiar smartphone technologies and commercially-available apps. The naturalistic design of this research is unique in this field, with participants recruited from the community rather than in- or out-patient cohorts (Beiwinkel et.al., 2016; Faurholt-Jepsen et.al., 2015; Faurholt-Jepsen, Vinberg et.al., 2016). The use of participants' own smartphone is also

relatively unique compared to the existing research. Familiarity with and established use of the device reduced any potential impacts resulting from learning new technologies, while the lack of obvious indicators their smartphone was a monitoring device reduced the risk of stigma or exposure of their disorder to the wider community. These factors contributed to increased ecological validity, where participants' patterns of social stimulation were accurate representations of daily life, serving as a base from which meaningful changes could be detected.

Finally, the strong clinical oversight built into this study was a significant strength. Participants benefitted from clinical confirmation and clarification of disorder and sub-type, increased liaison between treating professionals and more frequent symptom and risk evaluation. Anecdotally, participants reported multiple benefits of involvement in this research, including increased insight of the role of social stimulation in their symptomology, expanded practices of symptom and behaviour monitoring and increasing capacity to effectively discuss their symptoms with their treating professionals. Despite these being of benefit to the participants, it should be considered that such behavioural change may have impacted on the research findings.

#### 4.5 Limitations

The rapid evolution of social-media has yielded a plethora of new methods of communication (e.g. Facebook; WhatsApp; Twitter) which were beyond the scope of this research. An increasing trend towards integrated social-media messaging, where in-built SMS activities are subsumed into a social-media platform (e.g. Facebook Messenger), restricted the availability of SMS data for some participants.

Like most other research in this area, the UM and IFTTT apps were developed for Android operating systems, thus iPhone users were excluded from participation. Restrictions within the iPhone operating system prevent the passive collection of sensor data by third-party

apps, inhibiting remote access to this information. Although Android represents approximately three quarters of the market worldwide, iPhone holds approximately 60% of the Australian market (Stat Counter, n.d.). Indications that the choice of operating system can reflect underlying demographic differences, such as socioeconomic status (Harari et.al., 2016), imply that, as well as forming a significant barrier to ongoing recruitment of participants in the current study, the restriction of operating system may also represent a barrier to generalizability of results.

Within this cohort, there was limited variation in mood and few confirmed episodes of relapse against which objective data could be compared. The use of quarterly clinical assessment measures, designed to decrease participant burden, prevented the identification of mood episodes in the intervening period and limited the specificity of change point detection correlations. Additionally, a number of other underlying reasons for the lack of strong conclusions should be considered. Although a variety of CP detection methods exist, they remain largely untested in the realm of psychological time-series data. As such, the methods attempted within the current study may not have been the most appropriate to detect these changes. Alternatively, the sample size may have been too small to allow the detection of such changes if they did exist.

#### 4.6 Conclusion

The role of social stimulation, particularly telecommunications, is an important area where clinical monitoring can enhance psychological interventions for individuals with BD. Clinicians should include measures of social stimulation within their current symptom monitoring and stabilisation approaches, such as the DSSI and potentially objective monitoring systems, to enhance shared understanding of an individual's early-warning signs and effective early intervention. However, further research is required, and should incorporate a larger sample size, daily mood assessment, gender-balanced samples and a comparison

control group. Also, investigating the characteristics of iPhone users, and social-media telecommunications, is an important next step in understanding the role of social stimulation in BD, therefore continued focus on app development and third-party integration is vital. Finally, it will be important that future research balances the requirements of the monitoring technology with the practicalities of everyday smartphones and ethical considerations of behavioural monitoring. With these enhancements, objective, automated monitoring of lifestyle behaviours can improve the ability for individuals with BD to effectively selfmanage the course of their disorder and reduce relapse.

# **Tables**

Table 1

Participant characteristics at baseline

Characteristic $n = 12$						
Characteristic	<i>n</i> –12					
Age (years), mean (SD)	33.5 (8.3)					
Gender, female (%)	83.3					
Education level (%)						
Tertiary	50.0					
TAFE	41.7					
Secondary	8.3					
Employment status (%)						
Employed full-time	41.7					
Employed part-time	25.0					
Not employed	33.3					
Living with a spouse, number yes (%)	66.7					
Diagnosis (%)						
Bipolar I	41.7					
Bipolar II	58.3					
Time since initial diagnosis (years), mean (SD)	4.4 (3.6)					
Currently taking medication (%)	91.7					
Suicide attempt, number yes (%)	50.0					
Treating Professional (%)						
Psychiatrist	33.3					
Psychologist	41.7					
Both	8.3					
None (General Practitioner only)	16.7					

Table 2

Participant Compliance with Data Collection across 12-months

Participant	Duration of	Clinical assessments	Objective data recorded	
	participation <sup>a</sup> (days)	completed (% of 6)	(% of days)	
1	365	83.3%	50.1%	
2	365	100.0%	60.8%	
3	377	100.0%	80.6%	
4	367	100.0%	76.0%	
5	370	100.0%	85.7%	
6	366	66.7%	65.3%	
7 <sup>b</sup>	106	33.3%	0.0%	
8	365	83.3%	76.8%	
9	183	33.3%	62.3%	
10	368	100.0%	82.3%	
11 <sup>c</sup>	368	100.0%	50.8%	
12	183	50.0%	88.5%	

*Note*. <sup>a</sup> The duration of each individual's participation in the study concluded with either their 12-month review date, the expected date of their 12-month review (where they did not attend the 12-month review but did not formally withdraw from the study) or the date of notification of withdrawal from the study. <sup>b</sup> Participant did not provide objective data and was excluded from the analyses. <sup>c</sup> Participant did not provide objective SMS data, and objective call data had frequent periods of missing data, and was excluded from the analyses.

Table 3

Clinical Assessment Scores across 12-months (BDRS/YMRS/DSSI)

Participant	Measure	Baseline	1-week	3-month	6-month	9-month	12-month	M (SD)
	BDRS	1	32**	12*	16*	9*	-	14* (11.5)
1	YMRS	2	$8^*$	5	15 <sup>*</sup>	$9^*$	-	8 (4.9)
	DSSI	23	19	24	25	25	-	23 (2.5)
	BDRS	25**	13*	29**	6	10*	10*	16* (9.3)
2	YMRS	11*	9*	4	2	2	10	10 (9.3) 11* (6.8)
2	DSSI	14		15				
	DSSI	14	16	13	25	24	20	19 (4.7)
	BDRS	0	13*	19**	16*	7	$10^{*}$	11* (6.8)
3	<b>YMRS</b>	$9^{*}$	3	5	5	2	3	5 (2.5)
	DSSI	23	23	19	23	20	22	22 (1.8)
	DDDC	13*	15*	4	17**	0	10*	11* (4.0)
4	BDRS	13 9*	13 22**	4		8	10*	11*(4.8)
4	YMRS			7	7	0	10*	9* (7.2)
	DSSI	23	26	21	21	20	17	21 (3.0)
	BDRS	22**	16*	4	12*	5	3	10* (7.7)
5	<b>YMRS</b>	19**	0	$10^{*}$	7	4	3 2	7 (6.9)
	DSSI	19	19	20	27	26	23	22 (3.6)
	DDDC	29**	21**	17**	13*			20** (6.9)
6	BDRS	29 7		1 / 9*		-	-	20** (6.8)
6	YMRS		7		0	-	-	6 (3.9)
	DSSI	25	25	25	25	-	-	25 (0.0)
	BDRS	38**	26**	41**	23**	16*	-	29** (10.5)
8	<b>YMRS</b>	12*	$9^*$	16**	7	3	-	9 (4.9)
	DSSI	21	20	22	21	18	-	20 (1.5)
	BDRS	47**	22**					35** (7.7)
9		47 17**	8*	-	-	-	-	
9	YMRS	20	8 22	-	-	-	-	13* (6.4)
	DSSI	20	22	-	-	-	-	21 (1.4)
	BDRS	16*	10*	17**	14*	10*	25**	15* (5.6)
10	<b>YMRS</b>	5	6	6	6	$10^{*}$	4	6 (2.0)
	DSSI	24	25	25	24	25	24	25 (0.5)
	DDDC	18**	12*	22**				17** (5.0)
12	BDRS YMRS	18 23**	5	4	-	-	-	17** (5.0) 11* (10.7)
12					-	-	-	, ,
	DSSI	19	29	24	-	-	-	24 (5.0)
Cohort	BDRS	21** (14.9)	)18** (7.1)	18** (11.7	)15* (4.8)	9* (3.5)	12* (8.1)	
M (SD)	YMRS	11* (6.5)		7 (3.9)	6 (4.4)	4 (3.8)	4 (3.5)	
` '	DSSI	` /	,	22 (3.3)	` /	23 (3.2)	` /	
-	2001	21 (3.2)	(3.7)	<i>22</i> (3.3)	- 1 (2.1)	25 (3.2)	21 (2.0)	

*Note.* Berk Depression Rating Scale (BDRS),  $\geq 9 = \text{subsyndromal score (*)}$ , > 16 = clinical score (\*\*); Young

Mania Rating Scale (YMRS), ≥8 = hypomania (\*), >14 = mania (\*\*); Duke Social Support Inventory (DSSI).

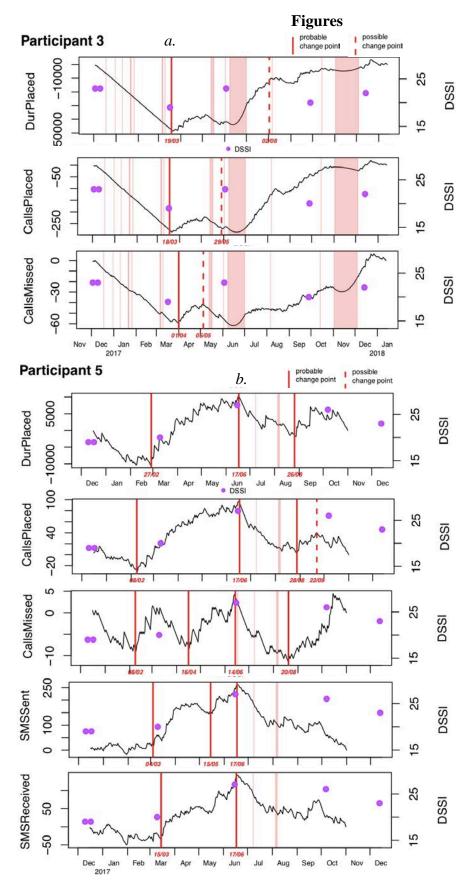


Figure 1. Examples of Correspondence between DSSI score and CP.

Note. Pink sections represent missing data; Red vertical lines represent change points (CP); black line and left Y-

axis represent CUSUM of data for each variable (DurPlaced = duration of calls placed (in seconds); CallsPlaced = number of calls made; CallsMissed = number of unanswered calls; SMSSent = number of SMS sent;

SMSReceived = number of SMS received); Purple dot and right Y-axis represent Duke Social Support Inventory (DSSI) score; X-axis represents time since baseline.

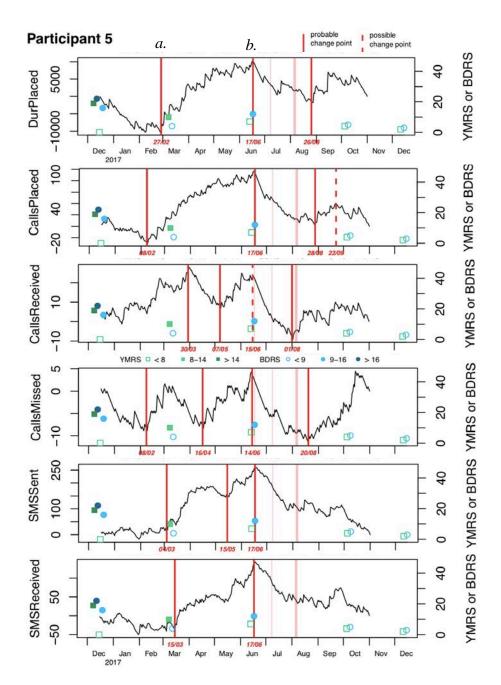


Figure 2. Example of Correspondence between BDRS and CP.

Note. Pink sections represent missing data; Red vertical lines represent change points (CP); Black line and left
Y-axis represent CUSUM of data for each variable (DurPlaced = duration of calls placed (in seconds);

CallsPlaced = number of calls made; CallsReceived = number of answered calls; CallsMissed = number of
unanswered calls; SMSSent = number of SMS sent; SMSReceived = number of SMS received); Green squares
and right Y-axis represent Young Mania Rating Scale (YMRS) scores (clear square = <8; light green square = 814; dark green square= >14); Blue circles and right Y-axis represent Berk Depression Rating Scale (BDRS)
scores (clear circle = <9; light blue circle = 9-16; dark blue circle = >16); X-axis represents time since baseline.

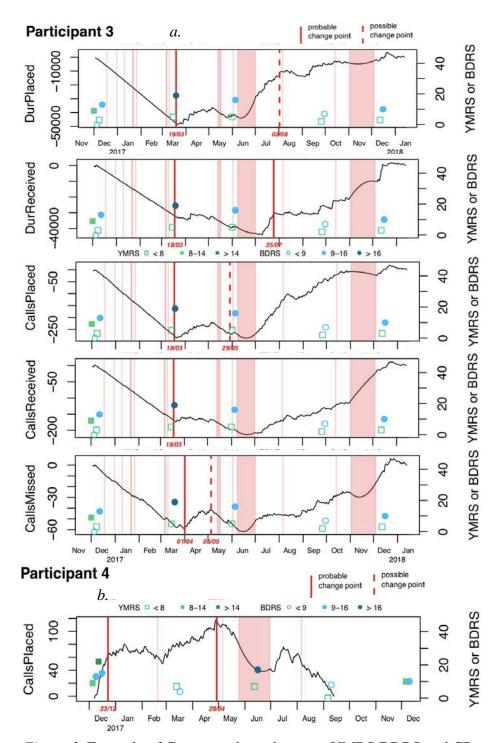


Figure 3. Example of Correspondence between YMRS/BDRS and CP.

Note. Pink sections represent missing data; Red vertical lines represent change points (CP); Black line and left

Y-axis represent CUSUM of data for each variable (DurPlaced = duration of calls placed (in seconds);

DurReceived = duration of calls received (in seconds); CallsPlaced = number of calls made; CallsReceived = number of answered calls; CallsMissed = number of unanswered calls); Green squares and right Y-axis represent

Young Mania Rating Scale (YMRS) scores (clear square = <8; light green square = 8-14; dark green square=

>14); Blue circles and right Y-axis represent Berk Depression Rating Scale (BDRS) scores (clear circle = <9; light blue circle = 9-16; dark blue circle = >16); X-axis represents time since baseline.

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# Appendix A

Instructions for Authors for the Journal of Affective Disorders

## **GUIDE FOR AUTHORS**

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The Journal of Affective Disorders publishes papers concerned with **affective disorders** in the widest sense: **depression, mania, anxiety and panic**. It is interdisciplinary and aims to bring together different approaches for a diverse readership. High quality papers will be accepted dealing with any aspect of affective disorders, including biochemistry, pharmacology, endocrinology, genetics, statistics, epidemiology, psychodynamics, classification, clinical studies and studies of all types of treatment.

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TIFF (or JPEG): Color or grayscale photographs (halftones), keep to a minimum of 300 dpi. TIFF (or JPEG): Bitmapped (pure black & white pixels) line drawings, keep to a minimum of 1000 dpi.

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- Supply files that are optimized for screen use (e.g., GIF, BMP, PICT, WPG); these typically have a low number of pixels and limited set of colors;
- Supply files that are too low in resolution;
- Submit graphics that are disproportionately large for the content.

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Please submit tables as editable text and not as images. Tables can be placed either next to the relevant text in the article, or on separate page(s) at the end. Number tables consecutively in

accordance with their appearance in the text and place any table notes below the table body. Be sparing in the use of tables and ensure that the data presented in them do not duplicate results described elsewhere in the article. Please avoid using vertical rules and shading in table cells.

# References

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Please ensure that every reference cited in the text is also present in the reference list (and vice versa). Any references cited in the abstract must be given in full. Unpublished results and personal communications are not recommended in the reference list, but may be mentioned in the text. If these references are included in the reference list they should follow the standard reference style of the journal and should include a substitution of the publication date with either 'Unpublished results' or 'Personal communication'. Citation of a reference as 'in press' implies that the item has been accepted for publication.

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- 3. *Three or more authors:* first author's name followed by 'et al.' and the year of publication. Citations may be made directly (or parenthetically). Groups of references should be listed first alphabetically, then chronologically.

Examples: 'as demonstrated (Allan, 2000a, 2000b, 1999; Allan and Jones, 1999). Kramer et al. (2010) have recently shown ....'

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Reference to a journal publication:

Van der Geer, J., Hanraads, J.A.J., Lupton, R.A., 2010. The art of writing a scientific article. J. Sci. Commun. 163, 51–59.

Reference to a book:

Strunk Jr., W., White, E.B., 2000. The Elements of Style, fourth ed. Longman, New York. Reference to a chapter in an edited book:

Mettam, G.R., Adams, L.B., 2009. How to prepare an electronic version of your article, in: Jones, B.S., Smith, R.Z. (Eds.), Introduction to the Electronic Age. E-Publishing Inc., New York, pp. 281–304.

Reference to a website:

Cancer Research UK, 1975. Cancer statistics reports for the UK.

http://www.cancerresearchuk.org/aboutcancer/statistics/cancerstatsreport/ (accessed 13 March 2003).

Reference to a dataset:

[dataset] Oguro, M., Imahiro, S., Saito, S., Nakashizuka, T., 2015. Mortality data for Japanese oak wilt disease and surrounding forest compositions. Mendeley Data, v1. https://doi.org/10.17632/xwj98nb39r.1.

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# Appendix B

# Human Research Ethics Committee Approval



#### **HUMAN RESEARCH ETHICS COMMITTEE**

### **Notification of Expedited Approval**

To Chief Investigator or Project Supervisor: Doctor Frances Kay-Lambkin

Cc Co-investigators / Research Students: Doctor Tanya Hanstock

**Professor Simon Dennis** 

**Conjoint Associate Professor Rachel Heath** 

Ms Catherine King Ms Madeleine Drew Ms Nicole Carter

Re Protocol: Utilising Life Logging and New Technologies to Help

Predict Relapse in Bipolar Disorder (Considered in

consultation with HNEHREC)

 Date:
 12-Aug-2016

 Reference No:
 H-2016-0067

 Date of Initial Approval:
 08-Aug-2016

Thank you for your **Response to Conditional Approval** submission to the Human Research Ethics Committee (HREC) seeking approval in relation to the above protocol.

Your submission was considered under Expedited review by the Chair/Deputy Chair.

I am pleased to advise that the decision on your submission is Approved effective 08-Aug-2016.

In approving this protocol, the Human Research Ethics Committee (HREC) is of the opinion that the project complies with the provisions contained in the National Statement on Ethical Conduct in Human Research, 2007, and the requirements within this University relating to human research.

Approval will remain valid subject to the submission, and satisfactory assessment, of annual progress reports. If the approval of an External HREC has been "noted" the approval period is as determined by that HREC.

The full Committee will be asked to ratify this decision at its next scheduled meeting. A formal *Certificate of Approval* will be available upon request. Your approval number is **H-2016-0067**.

If the research requires the use of an Information Statement, ensure this number is inserted at the relevant point in the Complaints paragraph prior to distribution to potential participants You may then proceed with the research.

## **Conditions of Approval**

This approval has been granted subject to you complying with the requirements for *Monitoring of Progress*, *Reporting of Adverse Events*, and *Variations to the Approved Protocol* as <u>detailed below</u>.

#### PLEASE NOTE:

In the case where the HREC has "noted" the approval of an External HREC, progress reports and reports of adverse events are to be submitted to the External HREC only. In the case of Variations to the approved protocol, or a Renewal of approval, you will apply to the External HREC for approval in the first instance and then Register that approval with the University's HREC.

#### Monitoring of Progress

Other than above, the University is obliged to monitor the progress of research projects involving human participants to ensure that they are conducted according to the protocol as approved by the HREC. A progress report is required on an annual basis. Continuation of your HREC approval for this project is conditional upon receipt, and satisfactory assessment, of annual progress reports. You will be advised when a report is due.

#### • Reporting of Adverse Events

- 1. It is the responsibility of the person first named on this Approval Advice to report adverse events.
- Adverse events, however minor, must be recorded by the investigator as observed by the investigator or
  as volunteered by a participant in the research. Full details are to be documented, whether or not the
  investigator, or his/her deputies, consider the event to be related to the research substance or
  procedure.
- 3. Serious or unforeseen adverse events that occur during the research or within six (6) months of completion of the research, must be reported by the person first named on the Approval Advice to the (HREC) by way of the Adverse Event Report form (via RIMS at <a href="https://rims.newcastle.edu.au/login.asp">https://rims.newcastle.edu.au/login.asp</a>) within 72 hours of the occurrence of the event or the investigator receiving advice of the event.
- 4. Serious adverse events are defined as:
  - o Causing death, life threatening or serious disability.
  - o Causing or prolonging hospitalisation.
  - o Overdoses, cancers, congenital abnormalities, tissue damage, whether or not they are judged to be caused by the investigational agent or procedure.
  - o Causing psycho-social and/or financial harm. This covers everything from perceived invasion of privacy, breach of confidentiality, or the diminution of social reputation, to the creation of psychological fears and trauma.
  - Any other event which might affect the continued ethical acceptability of the project.
- 5. Reports of adverse events must include:
  - o Participant's study identification number;
  - o date of birth;
  - o date of entry into the study;
  - o treatment arm (if applicable);
  - o date of event;
  - o details of event;
  - o the investigator's opinion as to whether the event is related to the research procedures; and o action taken in response to the event.
- Adverse events which do not fall within the definition of serious or unexpected, including those reported from other sites involved in the research, are to be reported in detail at the time of the annual progress report to the HREC.

#### Variations to approved protocol

If you wish to change, or deviate from, the approved protocol, you will need to submit an *Application for Variation to Approved Human Research* (via RIMS at <a href="https://rims.newcastle.edu.au/login.asp">https://rims.newcastle.edu.au/login.asp</a>). Variations may include, but are not limited to, changes or additions to investigators, study design, study population, number of participants, methods of recruitment, or participant information/consent documentation. **Variations must be approved by the (HREC) before they are implemented** except when Registering an approval of a variation from an external HREC which has been designated the lead HREC, in which case you may proceed as soon as you receive an acknowledgement of your Registration.

#### Linkage of ethics approval to a new Grant

HREC approvals cannot be assigned to a new grant or award (ie those that were not identified on the application for ethics approval) without confirmation of the approval from the Human Research Ethics Officer on behalf of the HREC.

Best wishes for a successful project.

Professor Allyson Holbrook

Chair, Human Research Ethics Committee

For communications and enquiries:

**Human Research Ethics Administration** 

Research Services
Research Integrity Unit
NIER, Block C
The University of Newcastle
Callaghan NSW 2308
T +61 2 492 17894

Human-Ethics@newcastle.edu.au

RIMS website - <a href="https://RIMS.newcastle.edu.au/login.asp">https://RIMS.newcastle.edu.au/login.asp</a>

Linked University of Newcastle administered funding:

Funding body	Funding project title	First named investigator	Grant Ref

# Appendix C

# Human Research Ethics Approval Amendment

#### **HUMAN RESEARCH ETHICS COMMITTEE**

## **Notification of Expedited Approval**

To Chief Investigator or Project Supervisor: Associate Professor Frances Kay-Lambkin

Cc Co-investigators / Research Students: Mr Andrew Hide

Mr Gabe Heaton Dianne Head Renee Morrison Charlotte Jones

Doctor Tanya Hanstock Professor Simon Dennis

**Conjoint Associate Professor Rachel Heath** 

Ms Catherine King Ms Madeleine Drew Ms Nicole Carter

Re Protocol: Utilising Life Logging and New Technologies to Help

Predict Relapse in Bipolar Disorder (Considered in

consultation with HNEHREC)

Date: **4-May-2017**Reference No: **H-2016-0067** 

Thank you for your **Variation** submission to the Human Research Ethics Committee (HREC) seeking approval in relation to a variation to the above protocol.

Variation to add Andrew Hide as a Co-Investigator, Gabe Heaton, Dianne Head, Renee Morrison and Charlotte Jones as Student Researchers.

Your submission was considered under **Expedited** review by the Ethics Administrator.

I am pleased to advise that the decision on your submission is Approved effective 04-May-2017.

The full Committee will be asked to ratify this decision at its next scheduled meeting. A formal *Certificate of Approval* will be available upon request.

Associate Professor Helen Warren-Forward

## Chair, Human Research Ethics Committee

For communications and enquiries:

## **Human Research Ethics Administration**

Research & Innovation Services Research Integrity Unit NIER, Block C The University of Newcastle Callaghan NSW 2308 T +61 2 492 17894 Human-Ethics@newcastle.edu.au

RIMS website - https://RIMS.newcastle.edu.au/login.asp

## Linked University of Newcastle administered funding:

Funding body Funding project title	First named investigator	Grant Ref
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# Appendix D

# HNELHD Human Research Ethics Committee Approval



15 August 2016

Dr Tanya Hanstock School of Psychology Faculty of Science, Information & Technology University of Newcastle

Dear Dr Hanstock,

Re: Utilising Life Logging and New Technologies to Help Predict Relapse in Bipolar Disorder (16/03/16/4.05)

HNEHREC Reference No: 16/03/16/4.05 NSW HREC Reference No: HREC/16/HNE/65

Thank you for submitting the above application for single ethical review. This project was first considered by the Hunter New England Human Research Ethics Committee at its meeting held on **16 March 2016.** This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review. The Committee's Terms of Reference are available from the Hunter New England Local Health District website.

I am pleased to advise, the Hunter New England Human Research Ethics Committee has determined that the above protocol meets the requirements of the *National Statement on Ethical Conduct in Human Research* and following acceptance of the requested clarifications and revised study documentation by Dr Nicole Gerrand Manager, Research Ethics & Governance under delegated authority from the Committee, grants ethical approval of the above project.

The following documentation has been reviewed and approved by the Hunter New England Human Research Ethics Committee:

Document	Version	Date
NEAF [Submission Code: AU/1/EE6429]		
Revised Study Flyer		
Participant Information Sheet	Version 3	13 July 2016
Participant Consent Form	Version 2	28 May 2016
SCID-RV (for DSM-5®) Module A	Version 1.0.0	
SCID-RV (for DSM-5®) Module D	Version 1.0.0	
The Bipolar Depression Rating Scale (BDRS)		
Self-Report Stimulation Measures		
Young Mania Rating Scale (YMRS)		

**Hunter New England Research Ethics & Governance Office** 

Locked Bag No 1

New Lambton NSW 2305 Telephone: (02) 49214950

Email: HNELHD-HREC@hnehealth.nsw.gov.au

http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx

International Physical Activity Questionnaire (IPAQ)	August 2012
Weekly Mood Rating	
Pittsburgh Sleep Quality Index (PSQI)	
Initial Intake of Participants in The Bipolar Study (Interview	
Script)	

# For the study: Utilising Life Logging and New Technologies to Help Predict Relapse in Bipolar Disorder

Approval has been granted for this study to take place at the following site:

## - Hunter New England Mental Health

Approval from the Hunter New England Human Research Ethics Committee for the above protocol is given for a maximum of **5** years from the date of this letter, after which a renewal application will be required if the protocol has not been completed.

The *National Statement on Ethical Conduct in Human Research (2007)*, which the Committee is obliged to adhere to, include the requirement that the committee monitors the research protocols it has approved. In order for the Committee to fulfil this function, it requires:

- A report of the progress of the above protocol be submitted at 12 monthly intervals. Your
  review date is August 2017. A proforma for the annual report will be sent two weeks prior to
  the due date.
- A final report must be submitted at the completion of the above protocol, that is, after data analysis has been completed and a final report compiled. A proforma for the final report will be sent two weeks prior to the due date.
- All variations or amendments to this protocol, including amendments to the Information Sheet and Consent Form, must be forwarded to and approved by the Hunter New England Human Research Ethics Committee prior to their implementation.
- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
  - any serious or unexpected adverse events
    - Adverse events, however minor, must be recorded as observed by the Investigator or as volunteered by a participant in this protocol. Full details will be documented, whether or not the Investigator or his deputies considers the event to be related to the trial substance or procedure. These do not need to be reported to the Hunter New England Human Research Ethics Committee
    - Serious adverse events that occur during the study or within six months
      of completion of the trial at your site should be reported to the Manager,
      Research Ethics & Governance Office, of the Hunter New England
      Human Research Ethics Committee as soon as possible and at the latest
      within 72 hours.
    - All other safety reporting should be in accordance with the NHMRC's Safety Monitoring Position Statement – May 2009 available at http://www.nhmrc.gov.au/health\_ethics/hrecs/reference/\_files/090609\_nhmrc\_position\_statement.pdf

**Hunter New England Research Ethics & Governance Office** 

Locked Bag No 1 New Lambton NSW 2305 Telephone: (02) 49214950

Email: HNELHD-HREC@hnehealth.nsw.gov.au

http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-

Unit.aspx

- · Serious adverse events are defined as:
  - Causing death, life threatening or serious disability.
  - Cause or prolong hospitalisation.
  - Overdoses, cancers, congenital abnormalities whether judged to be caused by the investigational agent or new procedure or not.
- Unforeseen events that might affect continued ethical acceptability of the project.
- If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand, as soon as possible.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Should you have any concerns or questions about your research, please contact Dr Gerrand as per the details at the bottom of the page. The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Please quote 16/03/16/4.05 in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Ms M Hunter

Chair

Hunter New England Human Research Ethics Committee

# Appendix E

# Updated HNELHD Human Research Ethics Approval



6 February 2018

Dr Tanya Hanstock School of Psychology Faculty of Science, Information & Technology University of Newcastle

Dear Dr Hanstock,

Re: Utilising Life Logging and New Technologies to Help Predict Relapse in Bipolar Disorder (16/03/16/4.05)

HNEHREC Reference No: 16/03/16/4.05 NSW HREC Reference No: HREC/16/HNE/65

Thank you for submitting the access request form for accessing participants, tissue and or data, but does not involve the conduct of research.

I am pleased to inform you that authorisation has been granted for a flyer advertising the above study to be displayed at the following facilities:

- Newcastle Adult Mental Health and Rehabilitation Team
- Lake Macquarie Adult Mental Health and Rehabilitation Team
- Hunter Valley Adult Mental Health and Rehabilitation Team
- Intermediate Stay Mental Health Unit

Please advise when the involvement of Hunter New England Local Health District in the above project has ended.

Yours faithfully

Dr Nicole Gerrand Research Ethics Officer Hunter New England Local Health District

Hunter New England Research Ethics & Governance Office

Locked Bag No 1 New Lambton NSW 2305

New Lambton NSW 2305 Telephone: (02) 49214950

Email: HNELHD-HREC@hnehealth.nsw.gov.au

http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx

# Appendix F

# Research Flyer

#### A/Prof Frances Kay Lambkin

Principal Investigator Lecturer School of Medicine and Public Health Old Waratah Post Office 22 Turton Road, Waratah NSW, 2298



# DO YOU HAVE BIPOLAR DISORDER?

Are you interested in participating in a 12-month study using the Fitbit Charge HR?

A study is being conducted which will track existing patterns of sleep, physical activity, socialisation, and mood in people who have a diagnosis of Bipolar Disorder I or II.

The Fitbit Charge HR will be provided to participants.

Individual face-to-face meetings with a member of our research team will also be required periodically over the course of the study at The Psychology Clinic at UoN.

The assessments including the time frame:

- 1. Initial assessment (2 hours)
- 2. A one week check in (1 hour)
- 3-month assessment (1 hour
- 6-month assessment (1 hour)
- 9-month assessment (1 hour)
- 12-month assessment (1 hour) 1-month post-study review (1 hour)
- 3-month post-study review (1 hour)
- 6-month post-study review (1 hour)

Participants will receive a small reimbursement for each stage of their participation.

Eligible participants will:

- have English as their first language;
- be aged between 18 and 50 years of age;
- currently be under the care of a GP/Psychiatrist;
- not have a serious medical condition (e.g. epilepsy, diabetes);
- have an Android smartphone.

If you would like to participate, or if you would like any additional information, please contact Dr Tanya Hanstock by email at Tanya.Hanstock@newcastle.edu.au or by phone on (02) 4921 5641.

#### Complaints about this research

This project has been approved by the University's Human Research Ethics Committee, Approval No. **H-2016-0067**08/08/2016. Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Senior Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 49216333, email human-ethics@newcastle.edu.au

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#### Appendix G

**Bipolar Depression Rating Scale** 

## The Bipolar Depression Rating Scale (BDRS)

#### **Rater Manual**

#### **General Instructions**

The BDRS is designed to measure the severity of depressive symptoms in bipolar depression. The BDRS is validated for clinical use by trained raters. The following conventions are designed to standardise scoring of the BDRS. Based on a clinical interview, the BDRS items rate the severity of depressive and/or mixed symptoms expressed by patients currently and during the past few days. If there is a discordance between symptoms currently and the last few days, the rating should reflect current symptoms. The scale contains 20 questions and the maximum score possible is 60. Higher scores indicate greater severity.

Individual items may be either subjective (patient report), objective (clinician rated) or a combination. In those combined items where there is a discrepancy between subjective and objective criteria, the objective should be more heavily weighted. If the rater believes the patient's score lies between two points of severity, and is unable to clarify with probing where a particular score lies, the more severe rating should be scored. When the operational definitions and suggestions for an item do not fully describe an individual situation, the categories of mild/moderate/severe should guide rating. Do not however ask patients to pick the right answer e.g. mild/moderate/severe.

In individuals with significant symptom lability, for example with ultra rapid or ultradian cycling, the rating should be weighted to the current mental state. When assessing the patient's current state, assessment should be done if possible without any attribution to environmental variables or medication status, e.g. use of hypnotics in assessing sleep. If a clear medical cause for a symptom is present, e.g. lithium tremor, this should not be rated. Some individuals who have chronic depression or alternate between depression and hypomania, may be unable to recall a period of well being, or be confident of what is normal for them. In items which refer to a person's usual self, it may be necessary for the interviewer to refer to hypothetical norms for those items.

Beware of central tendency error i.e. avoid assessing at a mid range as a "safe" response. Where examples are given e.g., 5 (3), the experience of one example satisfies the criteria. Is not necessary for any of the specific listed examples to be experienced if in the rater's judgement this criteria level is met. Do not take these anchor points too literally. The questions listed are a guide rather than a structured interview, and these need to be contextualised to the individual's clinical situation. Do not assume that because an individual does satisfy a particular anchor point that they will not satisfy the following anchor point. Rater's should consider both the frequency, duration and severity of the symptom, and when appropriate, associated features such as distress and impairment.

Following the generally agreed protocol in clinical interviewing, questions should move from general to specific. Patients generally are given as few prompts as possible to elicit the information required to obtain a rating. Within each item, questions should move from more open ended to more structured as needed. Raters should be aware of maintaining a balance between minimizing prompting but ensuring sufficient information is elicited to make the rating accurate and representative of the patient's symptomatology. Particularly unwell patients may generally be expected to need further prompting whereas higher functioning patients may be able to answer questions with less additional input from raters.

#### Criteria and components of the individual Items:

Before starting. I am going to ask you some questions about some symptoms you may have. When answering please keep in mind that we are focusing only on how you are now and over the last few of days.

#### Item 1. DEPRESSED MOOD

Include self-report **and/or** observed behaviour.

To score 3 depression should be severe but need not be extreme.

How has your mood been over the last few days?

Have you felt depressed, sad or flat?

Do you experience emotions other than depression?

Have you had feelings of helplessness or hopelessness?

How do you feel about the future?

How intense are these feelings?

How persistent are these feelings?

- 1. Depressed Mood (Self reported and/or observed depression as evidenced by gloom, sadness, pessimism, hopelessness, and helplessness)
- 0 Nil
- 1 Mild [brief or transient periods of depression, or mildly depressed mood]
- 2 Moderate [depressed mood is clearly but not consistently present and other emotions are expressed, or depression is of moderate intensity]
- 3 Severe [pervasive or continuous depressed mood of marked intensity]

#### Item 2. SLEEP DISTURBANCE

Score either **insomnia** 2(a) or **hypersomnia** 2(b), compared to the person's normal sleep pattern. Rate sleep quantity independent of medication. Include daytime sleep and "dozing" as well as intermittent sleep when assessing total sleep time.

How has your sleep been over the last couple of days?

How many hours would you usually sleep when you are well?

Is your sleep broken?

Do you awake feeling refreshed?

How many hours in total have you been sleeping over the last couple of nights?

Do you nap or doze in the day? For how long?

How many hours more or less than usual are you sleeping?

2. Sleep Disturbance: score either A or B (Change in total amount of sleep over a 24 hour cycle, rated independent of the effect of external factors)

#### A: Insomnia (reduction in total sleep time)

- 0 Nil
- 1 Mild [up to 2 hours]
- 2 Moderate [2-4 hours]
- 3 Severe [more than 4 hours]

OR

#### B: Hypersomnia (increase in total sleep time, inclusive of daytime sleep)

- 0 Nil
- 1 Mild [less than 2 hours, or normal amount but non-restorative]
- 2 Moderate [greater than 2 hours]
- 3 Severe [greater than 4 hours]

#### Item 3. APPETITE DISTURBANCE

Score either 3(a) or 3(b) compared to their usual eating and appetite pattern.

How is your appetite?

Currently, do you want to eat more or less than usual?

Has your change in appetite altered the amount you actually have been eating?

Has food lost taste?

Do you have to push yourself to eat?

Are you comfort eating or snacking more than usual?

Do you have cravings, which lead to binges?

# 3. Appetite Disturbance: score either A or B (Change in appetite and food consumption, rated independent of the effect of external factors)

#### A: Loss of Appetite

- 0 Ni
- Mild [no change in food intake, but has to push self to eat or reports that food has lost taste]
- 2 Moderate [some decrease in food intake]
- 3 Severe [marked decrease in food intake, hardly eating]

#### OR

#### **B: Increase in Appetite**

- 0 Niil
- 1 Mild [no change in food intake, but increased hunger]
- 2 Moderate [some increase in food intake, e.g., comfort eating]
- 3 Severe [marked increase in food intake or cravings]

#### Item 4. REDUCED SOCIAL ENGAGEMENT

Assess any reduction of social and interpersonal interaction the participant experiences due to their avoidance or reluctance to engage in social contact. Rate in the context of what is normal for the individual.

Are you meeting or interacting with other people as usual?

Do you find it easy to be around other people at present?

Are you meeting or seeing the people you would normally meet?

Are you avoiding meeting or making contact with people?

To what extent are you avoiding contact with other people?

Do you avoid answering the phone or seeing visitors?

# 1. Reduced Social Engagement (Reports reduced social and interpersonal engagement

#### or interactions)

- 0 Nil [normal]
- Mild [slight reduction in social engagement with no impairment in social or interpersonal function]
- 2 Moderate [clear reduction in social engagement with some functional sequelae, e.g., avoids some social engagements or conversations]
- 3 Severe [marked reduction in social interaction or avoidance of almost all forms of social contact, e.g., refuses to answer the phone or see friends or family]

#### Item 5. REDUCED ENERGY AND ACTIVITY

Reduced energy and activity should be rated on the basis of subjective reports and consequent reduction in goal directed activity.

Do you find you have as much energy and drive as usual? Do you feel more tired than usual?

Do you find it takes more energy than usual to do things?
Do your limbs feel very tired or heavy?
Has this led to you reducing your usual activities?
Are there things you no longer do at all because of reduced energy?
Are you spending much more time in bed?

#### 5. Reduced Energy and Activity (Reduced energy, drive and goal directed behaviour)

- 0 Nil
- 1 Mild [able to engage in usual activities but with increased effort]
- 2 Moderate [significant reduction in energy leading to reduction of some role- specific activities]
- 3 Severe [leaden paralysis or cessation of almost all role specific activities, e.g., spends excessive time in bed, avoids answering the phone, poor personal hygiene]

#### Item 6. REDUCED MOTIVATION

Reduced motivation and drive should be rated on the basis of subjective reports and consequent reduction in goal directed activity.

Is your motivation or drive reduced?

Are you less interested in your usual activities?

Do you need to push yourself to do the things you usually do?

Are you doing the things you would usually do?

Have you stopped doing any things you would usually do?

Which things?

# 6. Reduced Motivation (Reports of subjective reduction in drive, motivation, and consequent goal directed activity)

- 0 Nil [normal motivation]
- 1 Mild [slight reduction in motivation with no reduction in function]
- 2 Moderate [reduced motivation or drive with significantly reduced volitional activity or requires substantial effort to maintain usual level of function]
- 3 Severe [reduced motivation or drive such that goal directed behaviour or function is markedly reduced]

#### Item 7. IMPAIRED CONSENTRATION AND MEMORY

This item examines an individual's concentration, their ability to sustain attention and short-term memory difficulties.

Do you find it hard to concentrate?
Does your attention wander more easily?
Are you more forgetful than usual?
How severe is this?
Do you have any difficulty with reading, driving or watching TV?
Does this affect your ability to function? How much?

# 7. Impaired Concentration and Memory (Subjective reports of reduced attention, concentration, or memory, and consequent functional impairment)

- 0 Nil
- Mild [slight impairment of attention, concentration, or memory with no functional impairment]
- 2 Moderate [significant impairment of attention, concentration, or forgetfulness with some functional impairment]
- 3 Severe [marked impairment of concentration or memory with substantial functional impairment, e.g., unable to read or watch TV]

#### Item 8. ANXIETY

This item assesses both reported levels of cognitive anxiety as well as somatic symptoms. The presence of significant somatic symptoms usually reflects higher anxiety unless these symptoms are due to another medical condition.

Have you been more anxious or tense than usual over the last few days?
Have you found yourself worrying about things that wouldn't usually bother you?
Are you experiencing any physical symptoms such as tremors/palpitations/dizziness/
light headedness/pins & needles/sweating/flushes/butterflies in the stomach/diarrhoea?
How intense is the anxiety?

How persistent is the anxiety?

Does it interfere with your ability to function?

- 8. Anxiety (Subjective reports of worry, tension, and/or somatic anxiety symptoms e.g., tremor, palpitations, dizziness, light-headedness, pins and needles, sweating, dyspnoea, butterflies in the stomach, or diarrhoea)
  - 0 Ni
  - 1 Mild [transient worry or tension about minor matters]
  - 2 Moderate [significant anxiety, tension, or worry, or some accompanying somatic features]
  - 3 Severe [marked continuous anxiety, tension, or worry that interferes with normal activity; or panic attacks]

#### Item 9. ANHEDONIA

Assesses person's reported ability to experience pleasure in usual activities.

Do you find things as enjoyable as usual? Do you still find any pleasure in the things that you usually enjoy? Which activities still give you pleasure? To what extent? Have you completely lost your ability to experience pleasure?

- 9. Anhedonia (Subjectively reduced ability to experience pleasure in usual activities)
  - 0 Nil
  - 1 Mild [slight reduction in pleasure from usually pleasurable activities]
  - 2 Moderate [significant reduction in pleasure from usually pleasurable activities; some pleasure from isolated activities retained]
  - 3 Severe [complete inability to experience pleasure]

#### Item 10. AFFECTIVE FLATTENING

This item rates the intensity and range of the individual's usual emotions. When giving examples to a patient, be aware that an example of feeling "unable to cry" may have gender specific connotations

Do you feel your mood is flat or as if your feelings are numbed?

Do you have less feelings for significant people in your life?

Do you find it harder to get excited, angry or worked up about things?

Do you sometimes feel as if you are numb or have no feelings left?

# 10. Affective Flattening (Subjective sense of reduced intensity or range of feelings or emotions)

- 0 Ni
- Mild [slight constriction of range of affect, or transient reduction in range or intensity of feelings]
- 2 Moderate [significant constriction of range or intensity of feelings with preservation of some emotions, e.g., unable to cry]
- 3 Severe [marked and pervasive constriction of range of affect or inability to experience usual emotions]

#### Item 11. WORTHLESSNESS

Assesses individual's feelings of self worth or self-confidence, compared to usual levels of self-esteem.

How is your sense of self worth or confidence?

Do you feel you are as worthy a person as anyone else?

Are you still able to see your positive qualities?

Do you feel others would be better off without you?

- 11. Worthlessness (Subjective sense, or thoughts, of decreased self-value or self-worth)
  - 0 Nil
  - 1 Mild [slight decrease in sense of self-worth]
  - 2 Moderate [some thoughts of worthlessness and decreased self-worth]
  - 3 Severe [marked, pervasive, or persistent feelings of worthlessness, e.g., feels others better off without them, unable to appreciate positive attributes]

#### Item 12. HELPLESSNESS AND HOPELESSNESS

This item assesses feelings of helplessness or hopelessness, gloom and despondency.

Do you feel optimistic or pessimistic about the future?

Do you feel you will be able to cope with the future?

Do you feel helpless or hopeless?

Are those feelings constantly there?

How intense are those feelings?

- 12. Helplessness and Hopelessness (Subjective sense of pessimism or gloom regarding the future, inability to cope, or sense of loss of control)
  - 0 Ni
  - 1 Mild [occasional and mild feelings of not being able to cope as usual; or pessimism]
  - 2 Moderate [often feels unable to cope, or significant feelings of helplessness or hopelessness which lift at times]
  - 3 Severe [marked and persistent feelings of pessimism, helplessness, or hopelessness]

#### Item 13. SUICIDAL IDEATION

Assesses reported thoughts of death and suicide.

Do you feel that life is not worthwhile or meaningless? Do you have thoughts of death or dying? Do you feel that you would be better off dead? Have you thought about ending your own life? Have you had thoughts about harming yourself?

Have you made any plans?

# 13. Suicidal Ideation (Thoughts or feelings that life is not worthwhile; thoughts of death or suicide)

- 0 Nil
- 1 Mild [thoughts that life is not worthwhile or is meaningless]
- 2 Moderate [thoughts of dying or death, but with no active suicide thoughts or plans]
- 3 Severe [thoughts or plans of suicide]

#### Item 14. GUILT

This item rates guilt, self-blame and remorse for real or past events. Rating varies according to extent to which person feels guilty or deserving of their fate.

Do you find yourself feeling guilty about things that have happened in the past?

Are you self critical about your role in things that have gone wrong?

How intense are these feelings?

Are they there some of the time or all of the time?

Do you think these feelings are excessive?

Do you feel in some ways that having this illness is a punishment?

# 14. Guilt (Subjective sense of self blame, failure, or remorse for real or imagined past errors)

- 0 Nil
- 1 Mild [slight decrease in self-esteem or increased self-criticism]
- Moderate [significant thoughts of failure, self-criticism, inability to cope, or ruminations regarding past failures and the effect on others; able to recognise as excessive]
- 3 Severe [marked, pervasive, or persistent guilt, e.g., feelings of deserving punishment; or does not clearly recognise as excessive]

#### Item 15. PSYCHOTIC SYMPTOMS

This item rates psychotic symptoms, increasing from over-valued ideas through to overt psychotic symptoms. Rate on the basis of interview and mental status examination. Some of the information for this item will have bee gleaned from previous items.

Do your feelings of guilt affect the things you do?

Are you feeling suspicious?

Have you had unusual experiences such as hearing voices or seeing visions?

Do you believe things other people regard as unusual?

## 15. Psychotic Symptoms (Presence of overvalued ideas, delusions, or hallucinations)

- 0 Nil [absent]
- 1 Mild [mild overvalued ideas, e.g., self-criticism or pessimism without clear effect on behaviour]
- Moderate [significant overvalued ideas with clear effect on behaviour, e.g., strong guilt feelings, clear thoughts that others would be better off without them]
- 3 Severe [clear psychotic symptoms, e.g., delusions or hallucinations]

#### The Mixed Subscale: Items 16-20

#### Item 16. |RRITABILITY

This item rates irritability and hostility. It is rated on the basis of subjective reports of irritability as well as observed behaviour.

Do you find things irritate you more than they would have previously? Do you show that you are irritated or can you keep the feelings inside? Have you acted 'out of character' due to your feelings of irritation? Have you lost your temper so that you shouted or broke things?

- 16. Irritability (Reports uncharacteristic subjective irritability, short fuse, easily angered, manifested by verbal or physical outbursts)
  - ) Ni
  - 1 Mild [slight subjective irritability; may not be overtly present]
  - 2 Moderate [verbal snappiness and irritability that is clearly observable in the interview]
  - 3 Severe [reports of physical outbursts, e.g., throwing/breaking objects, or markedly abusive verbal outbursts]

#### Item 17. LABILITY

This item rates both reported and observed mood lability.

Have you experienced mood swings over the last couple of days? How intense are these mood swings? How frequently does this happen?

- 17. Lability (Observed mood lability or reported mood swings)
  - 0 Nil
  - 1 Mild [subjective reports of mild increase in mood lability]
  - 2 Moderate [mood lability clearly observable, moderate in intensity]
  - 3 Severe [marked and dominant mood lability, frequent or dramatic swings in mood]

#### Item 18. INCREASED MOTOR DRIVE

This item rates both subjective and observed increases in motor drive and activity. This should include both goal directed and non-specific activity.

Have you been more active than usual over the past few days? Do you feel you have more energy and drive then usual? How much more?

Have you done more things because of this?

- 18. Increased Motor Drive (Subjective reports and objective evidence of increased motor drive and motor activity)
  - 0 Nil [normal motor drive]
  - 1 Mild [slight increase in drive, not observable in interview
  - 2 Moderate [clear and observable increase in energy and drive
  - 3 Severe [marked or continuous increase in drive]

#### Item 19. INCREASED SPEECH

This item scores increased rate and quantity of speech or thought. It is predominantly an observer based rating, although subjective reports are taken into account.

Do you find you want to talk more than you usually would?
Do you find you interrupt people more than you usually would?
Are your thoughts going faster than usual?
Do you find yourself bursting with ideas that you want to tell people?

# 19. Increased Speech (Observed increase in either the rate or quantity of speech, or observed flight of ideas)

- 0 Nil
- 1 Mild [slight increase in the rate or quantity of speech]
- 2 Moderate [racing thoughts, significantly more talkative, clearly distractible, or some circumstantiality; does not impede interview]
- 3 Severe [flight of ideas; interferes with interview]

#### Item 20. AGITATION

This item rates observed restlessness and agitation, although subjective reports are taken into account.

Do you find you are more restless than usual? Do you feel agitated? Do you find it hard to sit still? How intense are these feelings?

#### 20 Agitation (Observed restlessness or agitation)

- 0 Nil [normal]
- 1 Mild [slight restlessness]
- 2 Moderate [clear increase in level of agitation]
- 3 Severe [marked agitation, e.g., near continuous pacing or wringing hands]

#### **Appendix H**

#### Young Mania Rating Scale

## **Young Mania Rating Scale (YMRS)**

Guide for Scoring Items – The purpose of each item is to rate the severity of that abnormality in the patient. When several keys are given for a particular grade of severity, the presence of only one is required to qualify for that rating.

The keys provided are guides. One can ignore the keys if that is necessary to indicate severity, although this should be the exception rather than the rule.

Scoring between the points given (whole or half points) is possible and encouraged after experience with the scale is acquired. This is particularly useful when severity of a particular item in a patient does not follow the progression indicated by the keys.

#### 1. Elevated Mood

- 0 Absent
- 1 Mildly or possibly increased on questioning
- 2 Definite subjective elevation; optimistic, selfconfident; cheerful; appropriate to content
- 3 Elevated, inappropriate to content; humorous
- 4 Euphoric; inappropriate to content; singing

#### 2. Increased Motor Activity - Energy

- 0 Absent
- 1 Subjectively increased
- 2 Animated; gestures increased
- 3 Excessive energy; hyperactive at times; restless (can be calmed)
- 4 Motor excitement; continuous hyperactivity (cannot be calmed)

#### 3. Sexual Interest

- 0 Normal; not increased
- 1 Mildly or possibly increased
- 2 Definitive subjective increase on questioning
- 3 Spontaneous sexual content; elaborates on sexual matters; hypersexual by self-report
- 4 Overt sexual acts (towards patients, staff, or interviewer)

#### 4. Sleep

- 0 Reports no decrease in sleep
- Sleeping less than normal amount by up to one hour
- 2 Sleeping less than normal by more than one hour
- 3 Reports decreased need for sleep
- 4 Denies need for sleep

#### 5. Irritability

- 0 Absent
- 2 Subjectively increased
- 4 Irritable at times during interview; recent episodes of anger or annoyance on ward
- 6 Frequently irritable during interview; short, curt throughout
- 8 Hostile, uncooperative; interview impossible

#### 6. Speech (Rate and Amount)

- 0 No increase
- 2 Feels talkative
- 4 Increased rate or amount at times, verbose at times
- 6 Push; consistently increased rate and amount; difficult to interrupt
- 8 Pressured; uninterruptible, continuous speech

#### 7. Language - Thought Disorder

- 0 Absent
- 1 Circumstantial; mild distractibility; quick thoughts
- 2 Distractible; loses goal of thought; changes topics frequently; racing thoughts
- 3 Flight of ideas; tangentiality; difficult to follow; rhyming; echolalia
- 4 Incoherent; communication impossible

#### 8. Content

- 0 Normal
- 2 Questionable plans, new interests
- 4 Special project(s); hyperreligious
- 6 Grandiose or paranoid ideas; ideas of reference
- 8 Delusions; hallucinations

#### 9. Disruptive – Aggressive Behavior

- 0 Absent; cooperative
- 2 Sarcastic; loud at times; guarded
- 4 Demanding; threats on ward
- 6 Threatens interviewer; shouting; interview difficult
- 8 Assaultive; destructive; interview impossible

#### 10. Appearance

- O Appropriate dress and grooming
- 1 Minimally unkempt
- Poorly groomed; moderately disheveled; overdressed
- 3 Disheveled; partly clothed; garish makeup
- 4 Completely unkempt; decorated; bizarre garb

#### 11. Insight

- O Present; admits illness; agrees with need for treatment
- 1 Possibly ill
- 2 Admits behavior change, but denies illness
- 3 Admits possible change in behavior, but denies illness
- 4 Denies any behavior changes

Name:		•
Rater: _		
Date: _	-	
Score:	-	

#### Appendix I

#### Duke Social Support Index – 10 Item Version

## DSSI-10

10-item Duke Social Support Index

- 1. Other than members of your family how many persons in your local area do you feel you can depend on or feel very close to?
- 2. How many times during the past week did you spend time with someone who does not live with you, that is, you went to see them or they came to visit you or you went out together?
- 3. How many times did you talk to someone (friends, relatives or others) on the telephone in the past week (either they called you, or you called them)?
- 4. About how often did you go to meetings of clubs, religious meetings, or other groups that you belong to in the past week?
- 5. Does it seem that your family and friends (people who are important to you) understand you?

Hardly Ever Some of the time Most of the time

- 6. Do you feel useful to your family and friends (people important to you)?

  Hardly Ever Some of the time Most of the time
- 7. Do you know what is going on with your family and friends?

  Hardly Ever Some of the time Most of the time
- 8. When you are talking with your family and friends, do you feel you are being listened to?

Hardly Ever Some of the time Most of the time

- 9. Do you feel you have a definite role (place) in your family and among your friends?

  Hardly Ever Some of the time Most of the time
- 10. Can you talk about your deepest problems with at least some of your family and friends?

Hardly Ever Some of the time Most of the time

DSSI-10 items, response options and scoring system from Pachana, N. A., Smith, N., Watson, M., McLaughlin, D., & Dobson, A. (2008). Responsiveness of the Duke Social Support sub-scales in older women. *Age and Ageing*, *37*, 666–672. doi:10.1093/ageing/afn205Appendix 2 of supplementary data on the journal website http://www.ageing.oxfordjournals.org. Contact: Nancy A Pachana, School of Psychology, University of Queensland, Brisbane Qld, 4072, Australia. Tel: (+61) 7 3365 6832; Fax: (+61) 7 3365 4466. Email: n.pachana@psy.uq.edu.au

## **SCORING**

Item 1: Item 2: o None = 1;  $\circ$  None = 1; o 1-2 people = 2;  $\circ$  Once, twice = 2 o More than 2 people = 3.  $\circ$  Three to seven or more = 3 Items 3 and 4: Items 5 to 10 o None, once = 1; o Hardly ever = 1 Some of the time = 2  $\circ$  Twice to five times = 2,  $\circ$  Most of the time = 3  $\circ$  Six or more times = 3.

## Social interaction sub-scale

- o Sum the re-coded scores for items 1 to 4
- o Range: 4-12
- o Higher scores indicate more social interaction

# Subjective support sub-scale

- o Sum the coded responses for items 5 to 10
- o Range: 6 to 18
- o Higher scores indicate more social support

# Research on Validity

Validated in general adult population (2010 Arizona Health Survey data n= 8215) "Researchers may confidently use DSSI-10 to measure social support for diverse adult populations. This instrument can be used in epidemiological studies to increase understanding of mental and physical health in relationship to social supports in the general population."

Validated in adult female population Australian Longitudinal Study on Women's Health (ALSWH) n=8,630

"Although the sub-scales of the DSSI may not fully reflect the complexity of social support paradigms, they are responsive to changes in the lives of older women and can be useful in community-based epidemiological studies"

#### Appendix J

#### **Participant Information Statement**

#### **Associate Professor Frances Kay Lambkin**

School of Health & Public Medicine University of Newcastle University Dr, Callaghan NSW 2308

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## Information Statement for the Research Project: Lifelogging and Bipolar Disorder

Document Version 3: 13/07/16

#### The Research Team:

Associate Professor Frances Kay-Lambkin, School of Medicine & Public Health

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Nicole Carter, Clinical Psychology Masters Candidate, School of Psychology
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Dianne Head, Clinical Psychology Masters Candidate, School of Psychology
Andrew Hide, Information and Technology Advisor, School of Psychology
Conjoint Associate Professor Rachel Heath, School of Psychology

Professor Simon Dennis, School of Psychology

You are invited to participate in the research project **Lifelogging and Bipolar Disorder**, which is being conducted by members of the above Research Team at the University of Newcastle.

The research is part of the studies of seven students (Nicole Carter, Madeleine Drew, Catherine King, Gabriel Heaton, Charlotte Jones, Renee Morrison and Dianne Head) in the Master of Clinical Psychology program at the University of Newcastle. It is also part of Dr Tanya Hanstock's (Senior Lecturer in the School of Psychology) PhD candidature in the School of Medicine and Public Health. These students are being supervised by Professor Simon Dennis (School of Psychology) and Associate Professor Frances Kay-Lambkin (School of Health and Public Medicine) and assisted with data analysis by Conjoint Associate Professor Rachel Heath (School of Psychology).

#### Why is the research being done?

This research project examines how lifestyle patterns can predict symptom changes in people diagnosed with Bipolar Disorder. We are particularly interested in examining patterns of sleep, physical activity, and social stimulation (how much socialising you do) as shown by people with Bipolar Disorder. Over a 12-month period, we will monitor these lifestyle activities via a Fitbit Charge HR (a fitness tracker), and two free android smartphone applications; Unforgettable Me (designed by researchers at the University of Newcastle), and the IF app which is commercially available. You will also be sent a text message with a link to a short online mood survey, which we will ask you to complete once a week. We hope that this research will help clinicians to predict and potentially prevent relapse in patients diagnosed with Bipolar Disorder.

#### Who can participate in the research?

You are invited to take part in this study because you responded to an advertisement that described the research project and what would be required of you. This study will be suitable for you if you:

- have a formal diagnosis of Bipolar Disorder Type I or Type II;
- have English as your first language;
- are aged between 18 and 50 years of age;
- are currently under the care of a GP or Psychiatrist;
- are stable on medication; and
- have an Android smartphone.

This study is not suitable for you if you have another serious medical condition (such as epilepsy or diabetes) or if you are acutely unwell, suicidal, have a brain injury, intellectual impairment or learning disorder.

#### What would you be asked to do?

If you agree to participate, you will be asked to attend the University of Newcastle Psychology Clinic (see attached map and parking information) on a Wednesday for six face-to-face assessments over the course of a 12-month period. These will include an initial assessment, an assessment one-week later to discuss any questions or concerns you might have about the study or the devices we are using to measure your behaviour, as well as assessments at 3, 6, 9, and 12 months after the initial assessment. We will also invite you to attend three follow-up visits; at 1, 3 and 6 months after we have completed the data collection. Each assessment will last for approximately one hour, except for the first visit, which will take up to two hours.

During the first face-to-face assessment, you will be asked to complete a number of questionnaires. These will ask you to provide information about your diagnosis, symptom severity, and lifestyle habits. We will also record your height and weight. At subsequent assessments, we will repeat some of these measures. The measurement devices we are using in this study will also be set up for you at this time.

At the first assessment, you will be provided with a Fitbit Charge HR (a wrist-worn fitness-tracking device), which we would like you wear for the 12 months of the study. The device will record your sleep-wake cycles and levels of physical activity. We will also set up the Android smartphone apps for you, and demonstrate how you can access the weekly online mood-rating questionnaire. Please see below for further information about how we will use these devices.

At this first assessment, you will also be asked for your consent so that the person conducting this assessment (Catherine, Nicole, Madeleine, Gabriel, Charlotte, Renee, Dianne or Tanya) can communicate with the health professional overseeing your mental health care and treatment. This person will be able to verify your diagnosis for our research purposes and ensure that your safety and wellbeing are maintained throughout the study. Please see the consent form for more information about the circumstances under which your health care professional may need to be contacted.

#### A Summary of the Assessments, their Durations and Reimbursements:

- 1. Start of study (2 hours) \$20
- 2. Week 2 assessment (1 hour) \$10
- 3. 3-month assessment (1 hour) \$10
- 4. 6-month assessment (1 hour) \$10
- 5. 9-month assessment (1 hour) \$10
- 6. 12-month assessment (1 hour) \$10
- 7. 1-month post-study review (1 hour) \$10
- 8. 3-month post-study review (1 hour) \$10
- 9. 6-month post-study review (1 hour) \$10

All assessments will occur at The University of Newcastle Psychology Clinic. When you complete the study, your total reimbursement will be \$100. We would also like to contact you after the study has been completed to invite you to take part in future studies related to Bipolar Disorder.

#### What choice do you have?

Participation in this research is entirely voluntary. Before you can take part, your informed consent will be required. Whether or not you decide to participate, your decision will not disadvantage you or affect the current treatment you are receiving, nor will it adversely affect your relationship with the University of Newcastle or the researchers.

Even if you do decide to participate in this project, you may withdraw at any time without giving a reason by contacting Associate Professor Kay-Lambkin whose contact details are at the top of this Information Sheet. If this does occur please let us know so we can assist you to deactivate all apps and accounts involved in data collection.

#### How much time will it take?

The data collection for this long-term project will take about 12 months with follow-up interviews occurring up to six months later. We will ask that you wear the Fitbit Charge HR device at all times, where possible, for a period of 12 months and attend six face-to-face assessments during this time. As stated above, the first assessment will take up to two hours, and each subsequent assessment will take approximately one hour. It should only take you about five minutes each week to complete a brief online mood-rating questionnaire once a week. When the 12-month data collection period has concluded, we will invite you to attend three face-to-face follow-up assessments after one, three and six months, each of these assessments taking approximately one hour.

#### What are the risks and benefits of your participating in this project?

Each participant will receive a Fitbit Charge HR. You will also be given a gift voucher at each face-to-face assessment you attend in order to reimburse you for your time associated with this research.

You may not benefit personally from participating in this research study. However, we hope to use the information you provide to monitor the progress of people diagnosed with Bipolar Disorder and improve our ability to predict relapse. By so doing, we hope to improve the quality of life for people diagnosed with Bipolar Disorder.

Some people experience skin irritation from wearing the Fitbit Charge HR on their wrist. Please contact the researchers if this occurs, as we will suggest other ways you can wear the Fitbit device so that this problem can be avoided.

A clinical psychologist, Dr Tanya Hanstock, will be available should you require psychological support during the face-to-face assessments. We have also provided you with the contact details of appropriate mental health services at the end of this document should you experience any distress while participating in this study.

#### How will your privacy be protected?

Only the members of the research team will have access to your identifiable information while they conduct face-to-face assessments with you, and contact your treating health professional in regards to these appointments. For all other research purposes, you will be given a participant number. In order to protect your confidentiality, this number will be used to identify all the information you provide for this project.

For specific information on how the automatically collected Fitbit and smartphone data will be accessed by the researchers, please read the technology information provided below. Wherever possible, we have indicated how you can examine and then possibly withdraw your data prior to it being accessed by the researchers.

Any information collected by the researchers that might identify you will be stored securely at the University of Newcastle and be accessible only by the researchers, unless you consent otherwise. There are limits to confidentiality, as required by law, and these will be discussed with you in detail in the first face-to-face meeting, prior to beginning the assessment. Data will be retained for at least five years. Your information will only be used for the purpose of this research study and it will only be disclosed without any personal identification with your permission.

#### How will the information collected be used?

The information collected from this research project will form a substantial component of the Masters theses to be submitted by the student researchers, Nicole Carter, Madeleine Drew and Catherine King. It also forms part of PhD research being conducted by Dr Tanya Hanstock. It is anticipated that the results of this research study will be published and/or presented in a variety of public forums. In any publication and/or presentation, information will be provided in such a way that you will not be able to be identified. Your data without identifiers may also be shared with other research groups to further our knowledge of Bipolar Disorder.

You have a right to receive feedback about the overall results of this study. If you request it, this feedback will be provided via email or post after the study has been completed.

#### What do you need to do to participate in this research project?

Please read this Information Statement carefully and be sure that you understand its contents before you consent to participate. If there is anything you do not understand, or if you have any questions, please contact Associate Professor Frances Kay-Lambkin, whose contact details are provided below.

If you would like to participate, please complete the attached Consent Form and return it directly to the researchers. Alternatively, you can return it to us via mail, addressed to Associate Professor Kay-Lambkin at the address at the top of this form. Please ensure you keep a copy of this Participant Information Statement for future reference throughout the study. A member of the research team will then contact you to arrange a convenient time for the initial interview.

#### Further information

If you would like further information about this study, please contact:
Associate Professor Frances Kay-Lambkin
School of Health & Public Medicine
University of Newcastle
University Dr, Callaghan NSW 2308

Phone: (02) 49854309

Email: Frances.Kaylambkin@newcastle.edu.au

## Thank you for considering this invitation.

## Complaints about the Conduct of this Research Project

This research has been approved by the University of Newcastle's Human Research Ethics Committee. Reference H-2016-0067.

Should you have concerns about your rights as a participant in this research, or if you have a complaint about the manner in which the research is being conducted, you may contact Associate Professor Kay-Lambkin, or if you would prefer to discuss the matter with an independent person please contact:

The Senior Human Research Ethics Officer Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan, NSW, 2308, Australia

NSW, 2308, Australia Phone: (02) 4921 6333 or

Email: human-ethics@newcastle.edu.au.

# INFORMATION ABOUT THE DEVICES AND COMPUTER PROGRAMS WE WILL BE USING IN THIS PROJECT

## Fitbit Charge HR

#### Fitbit Account Set-up and Privacy:

A Fitbit account and password has been set up for you using a free Gmail address and your participant ID instead of your name. This means that the researchers will only be able to see this code and they will not know whether the data belongs to you. Your information will be stored securely and only accessed by necessary members of the research team, using your participant ID, so that your identity will be protected and privacy maintained at all times. No identifiable data will be published. Your name will not appear on any data sets.

At the initial assessment the research team will assist you to install, then log in to the Fitbit app on your Android phone. You will be able to view your Fitbit results on your phone app or on the Fitbit Dashboard, which can be viewed on any web browser. The researchers will securely store these login details for the purposes of remotely accessing and downloading your data for analysis by logging into the Fitbit web interface.

Once your participation in the study has concluded we will assist you to transfer the Fitbit login to your name and to change the password. Once complete the research team will no longer have access to your account or data.

#### **Password Recovery:**

The Fitbit app will only require you to login once during set up. However, if your device is reset, or the application is re-installed you will need to re-enter your password. If you forget your password during the study, please contact Dr Tanya Hanstock for assistance. Please do not use the Fitbit password recovery service. Doing so will send a password reset request to the research team.

#### **Setting Up Your Fitbit Charge HR:**

In the initial appointment you will be shown how to turn on, calibrate, and sync your Fitbit with your Android smartphone.

#### How to wear the Fitbit Charge HR:

It is recommended that you wear the Fitbit charge HR on your non-dominant hand, one finger's width above the wrist bone, and not too tight, as suggested by Fitbit documentation. For better heart rate readings during exercise, it is recommended that you wear the band so that it's secure, but not too tight, and to wear the band higher on your wrist (about 2-3 finger widths above your wrist bone) and then to lower the band and loosen it after exercise, as suggested by Fitbit documentation.

Please note that the Fitbit Charge HR can cause skin irritation if worn constantly. If this occurs, please remove the device, seek first aid if necessary, and contact the Project Manager.

#### When to Wear the Fitbit Charge HR:

Please be aware that the Fitbit Charge HR is not waterproof. It will need to be removed before showering or partaking in aquatic sports and replaced as soon as possible afterwards. Please wear the Fitbit Charge HR throughout the day and while sleeping, except when showering, partaking in aquatic sports, and during recharging. During sleep recording, please leave the setting as "Normal," which is indicated as "appropriate for most users" by Fitbit documentation.

#### Charging the FitBit Charge HR:

The Fitbit Charge HR needs to be charged through a USB connection on either a computer or directly using a USB charging device, such as the one you use to recharge your Android smartphone. The battery lasts for up to five days, and it will need to be connected for several hours to recharge. You will receive a warning on the small screen of the Fitbit and in the app when you need to recharge the device. Try to recharge the Fitbit during the day so that the sleep measurements will not be disrupted.

#### **Syncing Your Data:**

The Fitbit device is automatically synchronized with your smartphone app whenever Bluetooth is enabled. If you are flying, setting your smartphone to airplane mode will not affect the recording of Fitbit data but no data will be transferred to your app during this time. Once you switch off airplane mode, Bluetooth will be enabled and data synchronization will resume. Whenever you attach your Fitbit to a computer via the USB cable, data will be automatically transferred to the application.

Please see https://help.fitbit.com for further information on device compatibility and features.

#### **Technical Assistance:**

If you have any problems with the technology for this study, please contact Dr Tanya Hanstock via email at Tanya.Hanstock@newcastle.edu.au

## Unforgettable Me

#### What is it?

The Unforgettable Me smartphone application automatically collects information about your physical activity, where you have been and what types of brief sounds you are hearing in your vicinity. No one will be able to detect what you have been saying based on these very short speech samples and your privacy will always be maintained. By tracking where you have been, using wifi and GPS signals, the researchers will be able to evaluate how much travel and how far you travel each day. The researchers will have a rough understanding of where you have been, but not precise locations. You can choose to delete these segments of data and will be shown how to do so.

#### **Account Set-up and Privacy:**

Unforgettable Me is an Android smartphone application developed by the University of Newcastle and available for download from the Google Play store. The data collected by the Unforgettable Me app is stored locally on your smartphone for a set number of days of your choosing (up to seven). After this, the data is automatically uploaded to the Unforgettable Me website (<a href="http://unforgettable.me">http://unforgettable.me</a>), where the research team will be able to remotely access and download your data. This means that the researchers will only be able to access your Unforgettable Me data once it is uploaded by the smartphone application to the website. You are able to access your data from within the app and select any data within the last seven days that you do not wish to share with the research team so that it will be excluded from this upload. You are also able to enter the app at any time and temporarily turn off the data collection for physical activity, location, and sound. These features will be set up and demonstrated to you during the initial assessment.

An Unforgettable Me account and password has been created for you. These login details will enable you to use the Unforgettable Me smartphone application. The researchers will also securely store these login details for the purposes of remotely accessing and downloading your data for analysis.

The account uses your participant ID instead of your name. This means that the researchers will only be able to see this code and they will not know whether the data belongs to you. Your information will be stored securely and only accessed by necessary members of the research team, using your participant ID, so that your identity will be protected and privacy maintained at all times. No identifiable data will be published. Your name will not appear on any data sets.

#### **Password Recovery:**

The Unforgettable Me application will only require you to login once during set up. However, if your device is reset, or the application is re-installed you will need to re-enter your password. If you forget your password, please contact Dr Tanya Hanstock for assistance.

#### **Charging Your Smartphone:**

The Unforgettable Me application will run in the background on your Android smartphone. Please make sure that your phone is recharged when its battery is low. If you have any problems with keeping your phone charged, please contact Dr Tanya Hanstock for assistance.

#### **Syncing Your Data:**

The Unforgettable Me app will upload data to its companion website when your phone is at least 90% charged and connected to Wi Fi so it will keep saving data for as many days as your phone has available space. The Unforgettable Me app will send your data to a secure computer at the University of Newcastle once every seven days by default. At any time before the seven days has expired, you can edit your data within the app. After this time, the data will be deleted from your phone and will only be accessible using the Unforgettable Me website. The researchers will show you how to do this at your initial assessment.

#### **Technical Assistance:**

If you have any problems with the technology for this study, please contact Dr Tanya Hanstock via email at Tanya.Hanstock@newcastle.edu.au

#### IFTTT – If This Then That

#### What is it?

The IF app (by IFTTT), is available on the Google Play store, and will be used to automatically create a record of answered, missed and dialled phone calls and sent and received SMS, and send it to the Unforgettable Me website where it will be stored and accessed by the researchers. The information collected will include the time of day and duration (for phone calls). Phone numbers will be obscured so that researchers will be able to analyse the quantity and frequency of contact with each obscured phone number. However, the actual phone numbers, names, and the content of SMS will not be recorded on the Unforgettable Me website.

#### **Account Set-up and Privacy:**

The IF application works by running an 'applet' to automatically collect the required information and send it to the Unforgettable Me website where it will be stored securely. An applet is triggered and executed each time your phone receives or sends an SMS, and each time you answer or miss a phone call or dial a phone number. The research team has already set up the applets for you.

There are five applets (Sent SMS, Received SMS, Calls outgoing, Calls missed, Calls answered). You will be able to temporarily turn off the 'applets' that record SMS and phone call data using a toggle from within the app if you want to temporarily stop sharing this data with the research team. Please remember to turn it back on from within the app when you wish to resume sharing this data. Logging out of the IF app will not stop data collection. Uninstalling the IF app will stop data collection until the IF app is reinstalled, at which time data collection will automatically resume. To permanently stop data collection once you have finished participating in the study, please turn off or delete the five applets used in this study or deactivate your IFTTT research account. To ensure your privacy, the research team will deactivate all research IFTTT accounts from the IFTTT website, as each participant finishes their participation in the study. You can continue to use the IF app in future for personal use by creating a new IFTTT account using your personal details.

If you wish to delete your data after it has been recorded you can do so using the Unforgettable Me website and your Unforgettable Me login. You will be shown how to do this in the initial assessment.

#### **Setting Up the IF App:**

In the initial appointment you will be assisted to install and set up the IF app on your Android smartphone using a pre-existing username and password.

#### **Charging Your Smartphone:**

This application will use a percentage of your smartphone battery charge. You may need to charge your phone slightly more frequently than you are used to. If you are experiencing trouble with the battery life of your phone and are unable to charge it frequently enough please contact Dr Tanya Hanstock.

#### **Syncing Your Data:**

The IFTTT app will need to use an Internet connection to send your data to the Unforgettable Me website. It will upload your data automatically whenever is has an Internet connection. The app settings can be used to toggle permission for the app to upload using cellular data or Wi-Fi only (default).

The data collected by IFTTT is automatically sent to the Unforgettable Me website so the research team will not be accessing your account on the IFTTT website during the study. However, the IFTTT app currently creates an activity record within your login that includes actual phone numbers, names, and a short preview of SMS content. This cannot be viewed unless logged into the account. Though the research team will not access this account during the study, you may wish to change your login details for this account. To do this, please log in on the IFTTT website using the login details we have provided to you. Navigate to Settings on the top right drop down menu. Please leave the username the same to protect your identity, but change both the password, and the email address (which is used for password recovery and important updates such as error messages for active applets). If there are any problems or errors with your IFTTT applets in the future we will discuss how to assist you with this while maintaining your privacy. You may need to come to the university if we cannot guide you over the phone.

#### **Technology Assistance:**

If you have any problems with your technology for this study, please contact Dr Tanya Hanstock via email at Tanya.Hanstock@newcastle.edu.au

#### **Mood Survey**

You will be asked to complete a brief, online mood-rating survey each week. A weekly reminder will be sent to your mobile phone prompting you to complete the survey via a web link contained within the SMS message. The survey should take no more than a few minutes to complete. The survey is most effective when completed as close to the time it is received as possible.

The survey asks you to rate how you feel at the moment and gives you a four-choice scale that you can use to rate your feelings. There is also a section for you to add additional comments if you wish. Your data will be sent to the researchers using your participant ID. No one will know that this data comes from you.

#### **Technology Assistance:**

If you have any problems with the technology for this study, please contact Dr Tanya Hanstock via email at <a href="mailto:tanya.hanstock@newcastle.edu.au">tanya.hanstock@newcastle.edu.au</a>

#### **Mental Health Services Contact Details**

#### **24 Hour Emergency Support:**

Lifeline (free call from mobile)	13 11 14
Lifeline Crisis Support Chat	www.lifeline.org.au/Get-Help/Online-Services/crisis-chat
Suicide Call Back Service	1300 659 467
NSW Mental Health Line	1800 011 511
Men's Helpline	1300 789 978
NSW Rural Mental Health Line	1800 656 463

#### **Psychiatric Emergency Care Centre**

Mater Mental Health Centre Edith St Waratah NSW 2298

Phone: 1800 011 511

#### Lake Macquarie Mental Health

Mater Mental Health Centre Edith St Waratah NSW 2298

Phone: 4033 5336

#### **Mental Health Substance Use (North)**

Edith St Waratah NSW 2298

Phone: 4033 5460

#### **Mental Health Substance Use (South)**

Edith St Waratah NSW 2298

Phone: 4033 5440

# Newcastle Adult Mental Health and Rehabilitation Team

Barrack Building James Fletcher Campus 72 Watt St Newcastle NSW 2300 Phone: 4964 7000, 4964 7001

# Lake Macquarie Adult Mental Health and Rehabilitation Team

James Fletcher Campus 72 Watt St Newcastle NSW 2300

Phone: 4904 9000, 4904 9049

#### Mental Health and Substance Use

McAuley Building
Mater Campus
Edith St Waratah NSW 2298
Phone: 4033 5600 4033 5606

Phone: 4033 5600, 4033 5606

#### **Hunter Valley Hospital Inpatient services:**

#### **Short Term Acute**

Maitland Hospital 550 High St Maitland NSW 2320

Phone: 4939 2456

#### **Adult Mental Health**

555 High St Maitland NSW 2320 Phone: 1800 011 511

#### **Hunter Valley Rehabilitation Team**

555 High St Maitland NSW 2320 Phone: 4939 2940

#### Appendix K

#### Consent Form

Associate Professor Frances Kay Lambkin School of Health & Public Medicine University of Newcastle University Drive, Callaghan NSW 2308

Phone: (02) 49854309

Email: Frances.Kaylambkin@newcastle.edu.au



## Consent Form for the Research Project: Lifelogging and Bipolar Disorder

Document Version 2: 28/05/16

I,	, agree to participate in the above
	(name of participant)

research project and give my consent freely.

I understand that this project will be conducted as described in the Participant Information Statement, a copy of which I have retained.

I understand that I can withdraw from the project at any time and do not have to give any reason for withdrawing, and that this will not affect the current or future care I receive from health services and any current or future association with the University of Newcastle. I understand that I have the right to withdraw from the study and not have any of my data used or I can withdraw from the study and choose to have my existing data used in the research.

#### I consent to:

- a) an initial and a one-week follow up face-to-face assessment.
- b) ongoing face-to-face assessments at 3, 6, 9 and 12 months after the start of the study.
- c) wearing of the FitBit Charge HR for 12 months.
- d) receiving a weekly text message with a link to an online mood survey for me to complete.
- e) being invited to participate in three follow up face-to-face assessments 1, 3 and 6 months after the 12-month period of data collection has finished.
- f) the researchers having access to my data obtained during my time in the study, including data from the FitBit charge HR, online survey, face-to-face assessments, and smartphone applications used in the study

I am also aware that the researchers will contact my treating General Practitioner (GP), Psychiatrist and/or Psychologist about my mental health history and treatment. The researchers and my treating professional/s will liaise with each other if I am showing signs of a relapse or have a relapse.

I give consent for the researchers to contact the following professionals who are involved in my treatment: Name of Treating Professional Place of Work I understand that my personal information will remain confidential to the researchers, except as required by law and departmental policy. I have had the opportunity to have questions answered to my satisfaction. I am aware that I may not receive any personal benefit from participating in this project. I understand that I may be given personal feedback after each assessment is completed. I would like a copy of the summary of research results. □ Yes  $\square$  No I would like to be contacted regarding future related research projects. □ Yes □ No I consent for my unidentified data to be available for future related projects that receive ethics approval. ☐ Yes  $\square$  No ............ Signature of participant Signature of witness

......Name of participant

Date

......

*Name of witness* 

......

Date

#### Appendix L

#### **Initial Assessment Questions**

#### **Initial Intake of Participants in The Bipolar Study**

(Give information form and go through this and the consent form) – limits to confidentiality (Ask participant to sign the consent form)

1. How did you hear about the study?

# Demographics (Date of Initial Assessment): (Assessing psychologist/title): (Name of Participant): (Participant Number): (Gender):

- 2. What is your date of birth?
- 3. What is your address?
- 4. What is your mobile number?
- 5. What is the best email address to contact you on if needed?
- 6. Who is your GP?
- 7. Do you have a treating Psychologist/Clinical Psychologist? (if so, who is this, how long have you been seeing them and how often do you see them?):
- 8. Do you have a treating Psychiatrist? (if so, who is this, how long have you been seeing them and how often do you see them?):
- 9. If there was an emergency or if we could not easily contact you, who would be the best contact for you? (Name, relationship and mobile number):

#### **Background Details**

- 1. How would you describe your relationship status (e.g., single, married, in a defacto relationship, divorced)?
- 2. Do you have any children (if so ages and gender)?
- 3. What is your current employment/study/financial benefit?
- 4. What is your highest level of education?
- 5. What is your current income (0-\$18,200, \$18,201-\$37,000, \$37,001-\$80,000, \$80,001-\$180,000, \$180,000 and over)
- 6. What is your current household income? (use above tax brackets)

#### **History and Symptoms of BD**

- 7. How old where you when you think you first had any symptoms of Bipolar Disorder?
- 8. How old were you when you were actually diagnosed (and year)?
- 9. What are your current diagnoses (include comorbidities)?
- 10. How many hospital admissions have you had? (at what age/year?)
- 11. Have you ever attempted suicide (age/year)?
- 12. Have you ever engaged in self-harm (age/year)?
- 13. Do you currently use any substances (type, how much and how often)?
- 14. Do you drink alcohol (type, how much and how often)?
- 15. Do you currently smoke cigarettes (how much and how often)?
- 16. What are your current medications?
- 17. How compliant are you with taking them?

- 18. Do you have any side effects from your medication?
- 19. Have you received any psychological help (when, for how long, what type of therapy, what type of psychologist)?
- 20. Are there any family history of MH Issues (esp. BD)?
- 21. Has anyone in your family died by suicide?

#### \*Administer the SCID-5 RV (BD section only)\*

#### **Clinician Rated:**

**BDRS** 

YMRS (this can be done after if needed)

#### **Physical Health Details**

- 22. Do you have any physical health issues?
- 23. Are you on any medications for these (which medication for which conditions, dose)?
- 24. Have you ever used a lifestyle-monitoring device before (if so which one/s, how long, how did you find it)?
- 25. Have you ever used a Mental Health phone app before (if so which one/s, how long, how did you find it)?

#### **Administer Measures**

**Client:** 

**PSQI** 

**IPAO-SF** 

**DSSI-10** 

#### **Personal Network**

\*Make sure participants have the same amount of time to complete this (15 mins)

#### **Travel**

#### **Socialisation**

Risk assessment using risk assessment sheet- only if this has been indicated that it is needed in the assessments

Devise safety plan using safety plan sheet – may need to ask their permission to contact the person they live with to let them know the situation and when you write to their treating professional include your assessment of the situation

Write down the username and password for the fitbit app and web browser/IF app/UM app and web browser for the participant – these should be the same for each participant.

Show them the list of health professionals on the PCIF form if they become unwell and need to see a health professional and can't get into their usual treating professionals.

Here are the dates/time of next follow up session (let them know we can post the parking pass out closer to the date) but if it is straight after the initial, can give them their one week post follow up parking pass then.

Here are the details of who you can contact between now and the follow up appointment if they have any questions or concerns.

Let them know we will be sending a letter to their treating professional stating they are now engaged in the study.

Do you have any questions or concerns re: the study?

Here is your gift voucher for coming today – make sure you mark it off the chart using the specific code

After they leave – do the scoring of each assessment using the spreadsheet if you have time

Send the letter to their treating professional

#### Appendix M

#### Follow-up Review Questions

#### Follow Up Review of Participants in The Bipolar Study

Remind the participant who you are, and that this is a follow up appointment for the Bipolar Study. Explain what number and length of time the follow up is (for example, this is the follow up appointment number and the next appointment will be 3 months from their initial assessment appointment). Explain to them how many more you would like them to attend. Check the dates with them regarding these. Explain that this will take 1hr. Make sure they have a parking pass.

#### **Demographics**

(Date of Follow up Assessment):

(Assessing psychologist/title):

(Name of Participant):

(Participant Number):

Ask them if they have any changes to their contact details since they started in the study? For example have they moved, change phone numbers etc?

Have you had any changes as to who is your:

GP: (if so write the details of the new GP)

Psychiatrist: (if so write the details of the new Psychiatrist)

Ask them how their BD has been since they entered the study? Write a short narrative

Have they had any episodes of:

Depression (if so how many and for how long was each one)

Hypomania/Mania (if so how many and for how long was each one)

Psychosis? (if so how many and for how long was each one)

Self-harm? (if so how many and for how long was each one)

Suicide attempts? (if so how many and for how long was each one)

Did they have to go to their GP or Psychiatrist for any appointments?

(Check whether these were previously scheduled or if they had any extra appointments)

Have they had to change medication? (if so what are they now on)

Have they had a hospital admission? (if so, where and for how long)

#### **Physical Health Details**

Have you had any changes in substance use?

Have you had any changes with alcohol intake?

Have you had any changes in smoking?

Have you had any changes in sleep/wake cycle?

Have you had any changes in exercise?

Have you had any changes in socialising?

Weight:

Calculate BMI (let them know this):

#### **Administer Measures**

Client:Clinician Rated:PSQI -BDRS -IPAQ-SFYMRS

DSSI-10

Personal Network Map

Travel

Socialisation

Risk assessment if needed?

#### **FitBit Information**

Remind the client what the study involves again

Ask them how they have been finding the fitbit (record some of the narrative)

What have they enjoyed about it?

Have they had any problems with it?

Have they been looking at their data?

Ask the participant if they think any of their sleep logs may have been when they were lying down still for over an hour (e.g watching t.v). If so, go through their sleep-wake data on the web browser and make a note of these logs here – date and time/duration of sleep log.

Give them their gift voucher for coming today.

Remind them of the dates/time of next follow up session (can give them parking permit on the day they next come in)

Give written details of who the client can contact between now and the follow up appointment if they have any questions or concerns – info on their participant information form

Did the client have any questions or concerns re: the study?

Is the participant still keen to be in the study?

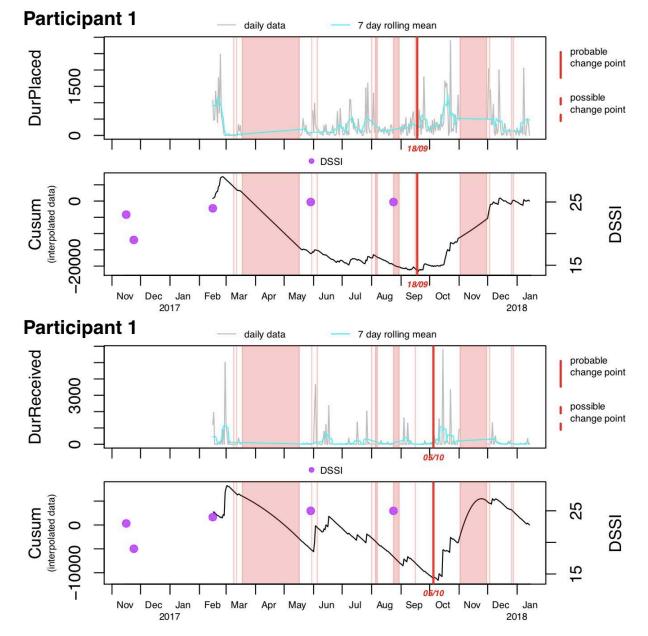
Have they completed this weeks mood survey?

Tell them you will be writing to their treating professional to ask about relapses.

Thank the participant for their time and for taking part in the study.

Appendix N

Participant Plots with Change Points and Social Stimulation Measure

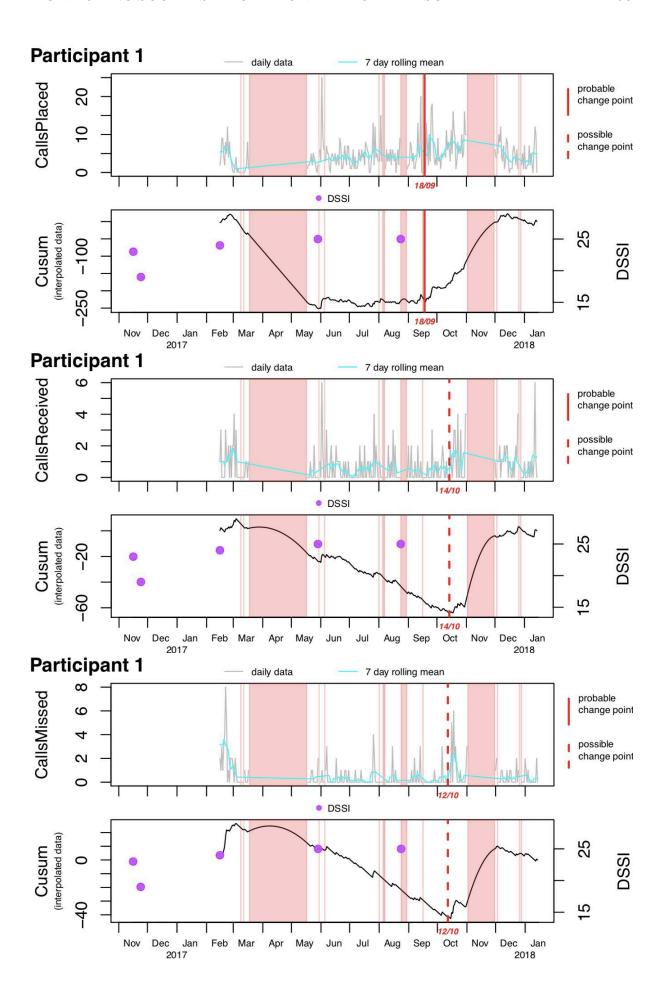


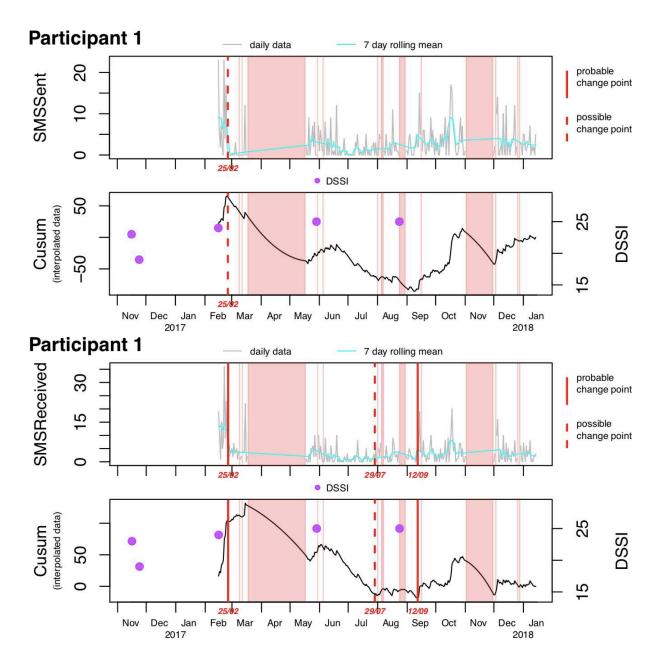
Note. Pink sections represent missing data; Red vertical lines represent change points (CP); black line and left
Y-axis represent CUSUM of data for each variable (DurPlaced = duration of calls placed (in seconds);

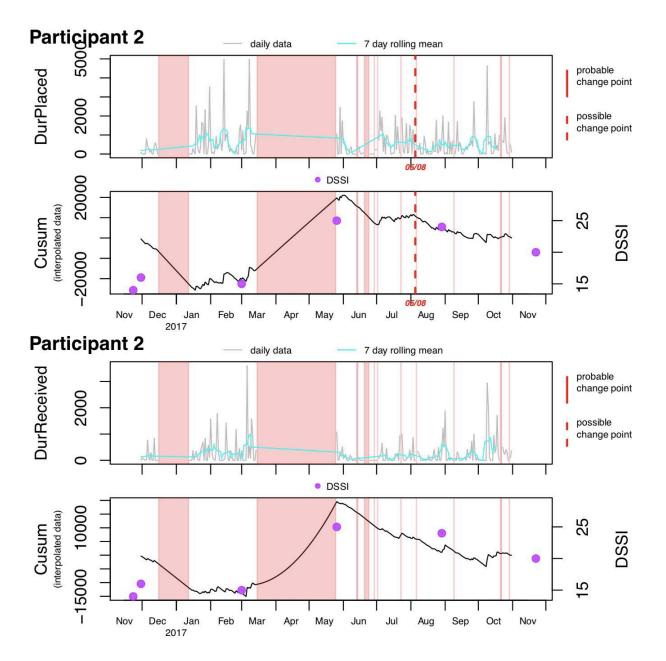
CallsPlaced = number of calls made; CallsMissed = number of unanswered calls; SMSSent = number of SMS

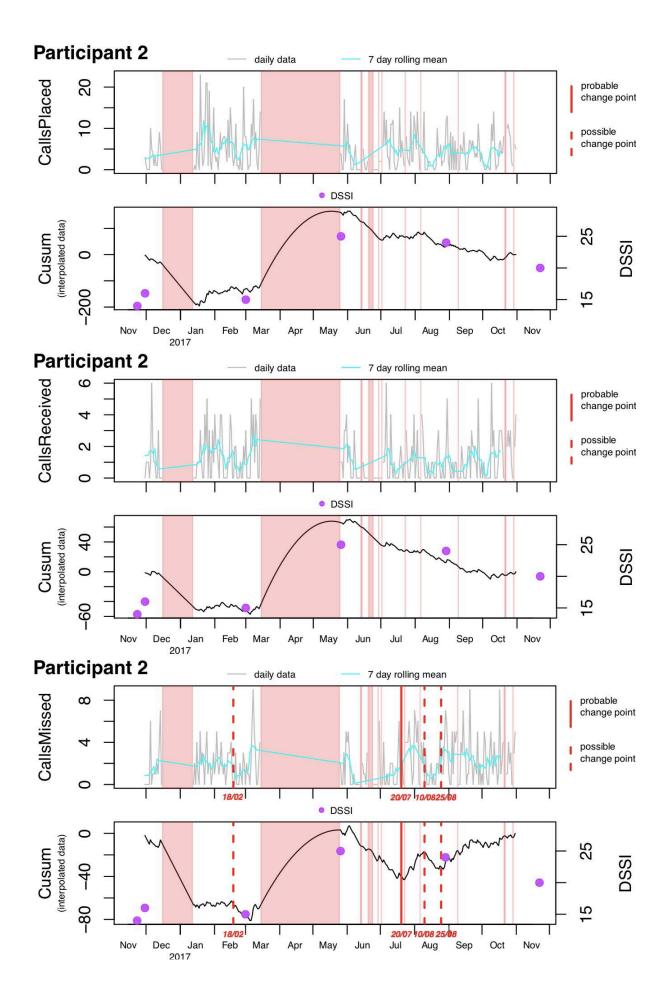
sent; SMSReceived = number of SMS received); Purple dot and right Y-axis represent Duke Social Support

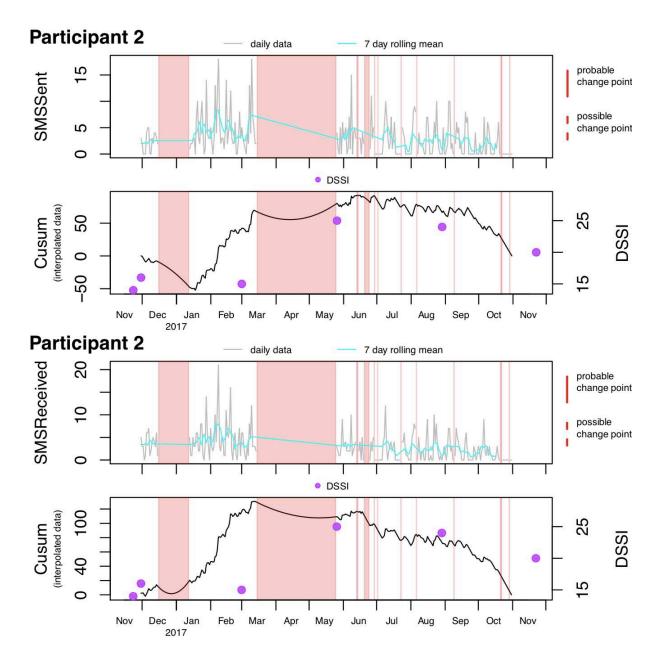
Inventory (DSSI) score; X-axis represents time since baseline.

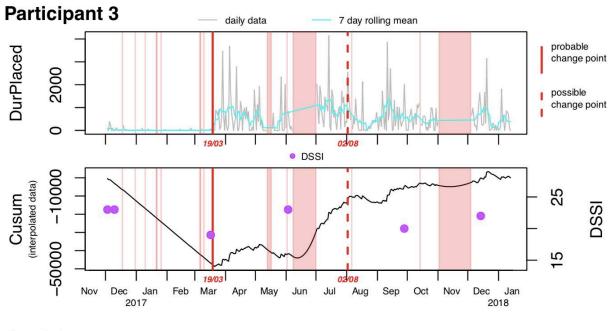


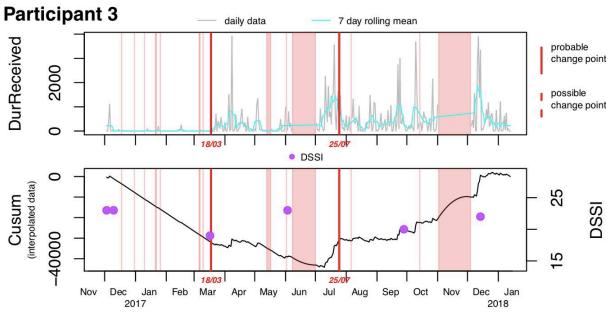


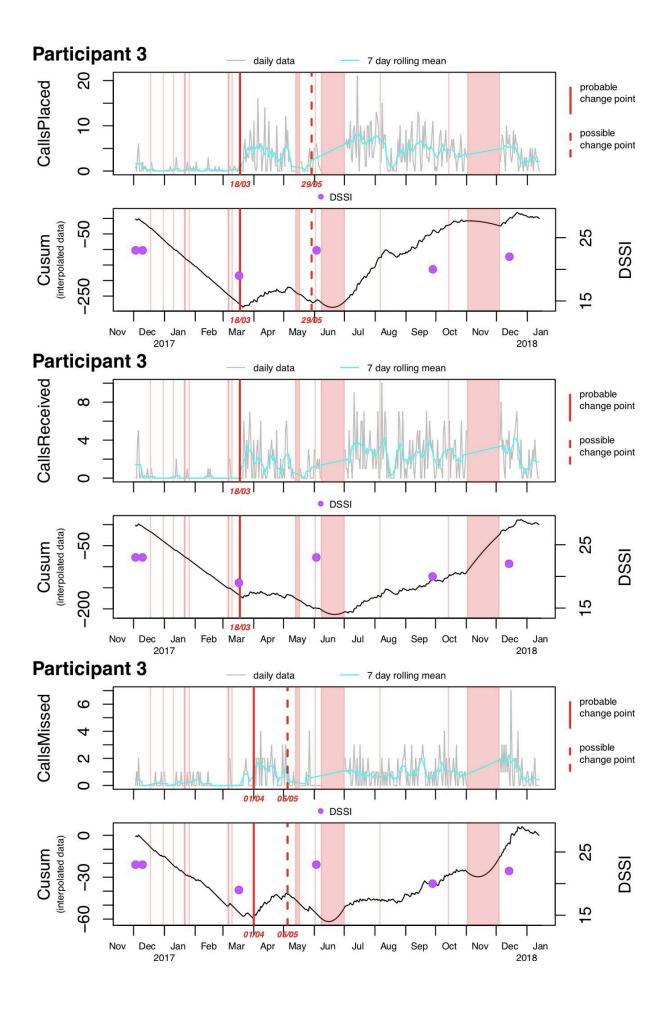


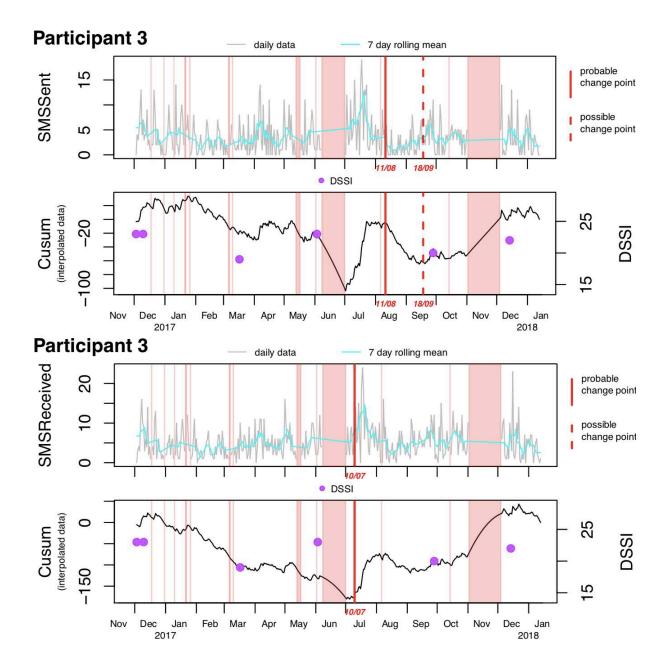


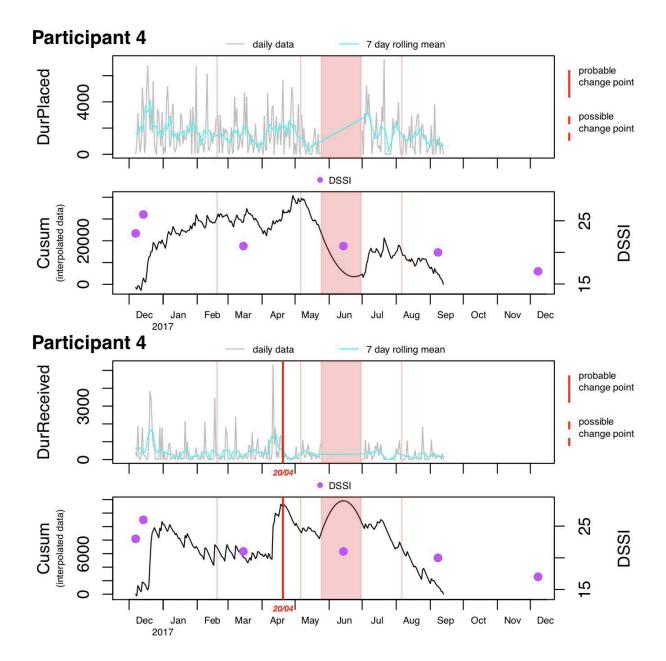


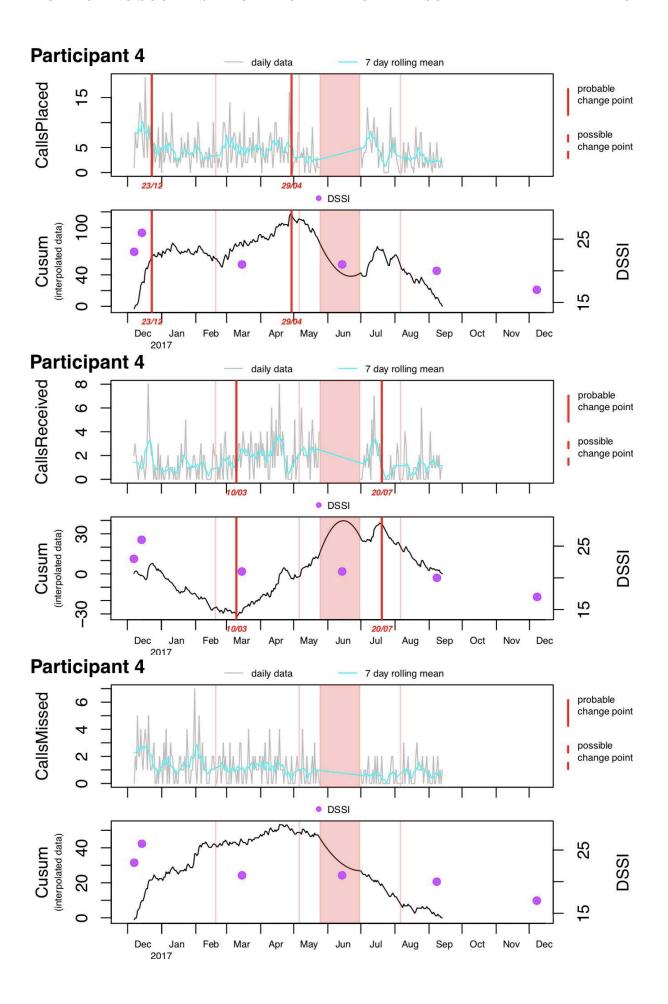


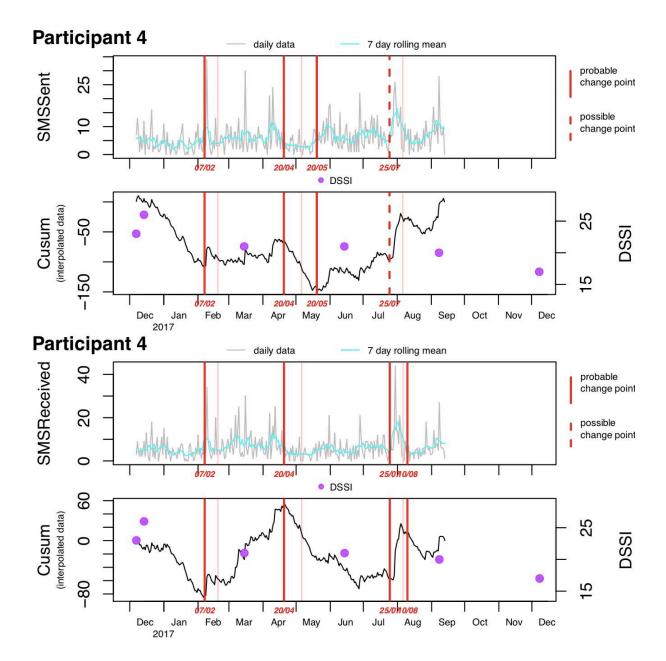


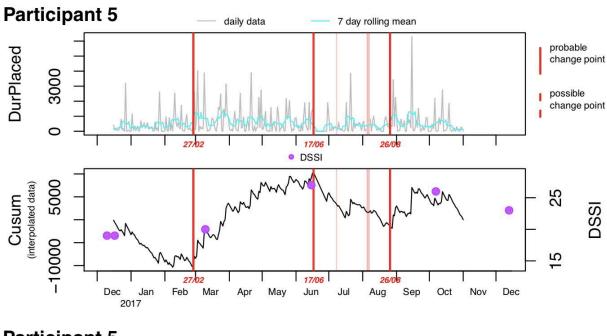


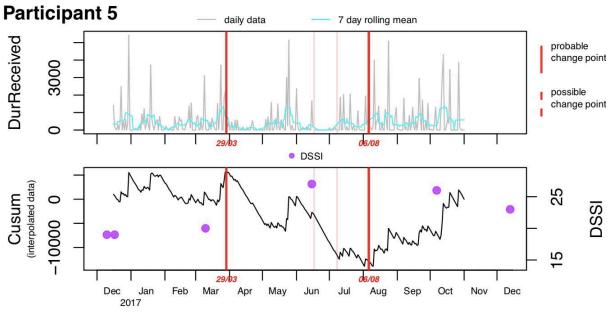


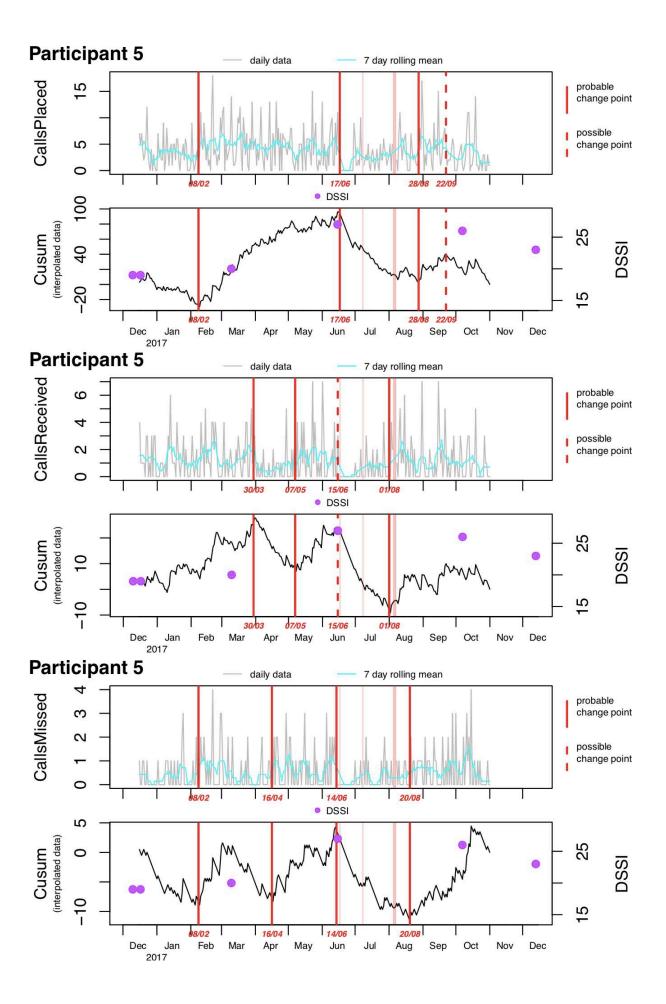


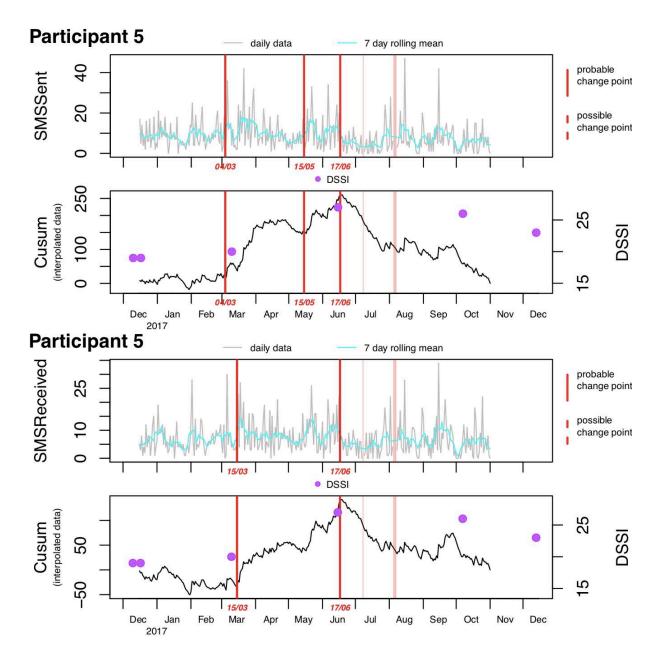


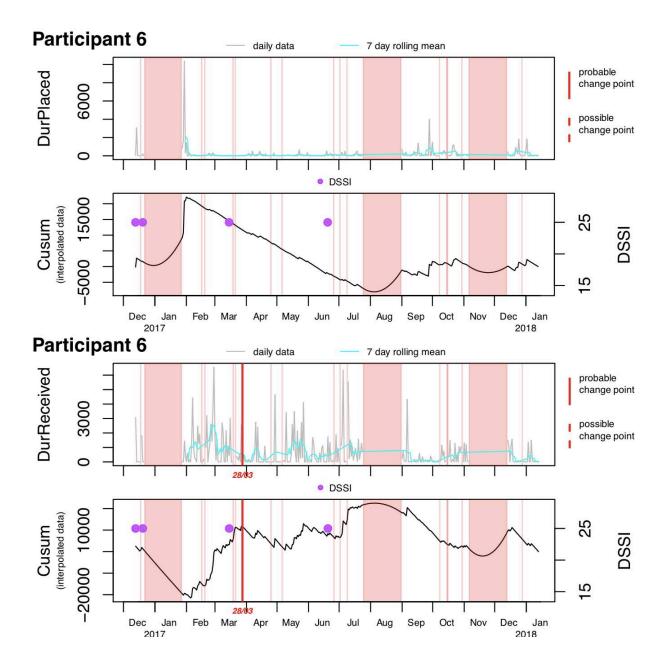


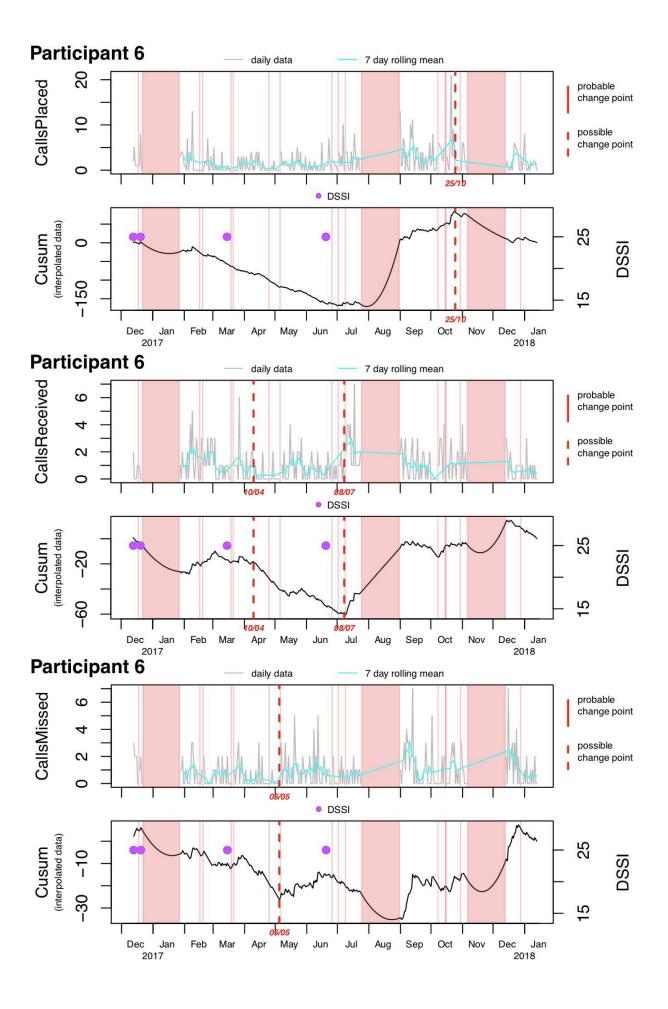


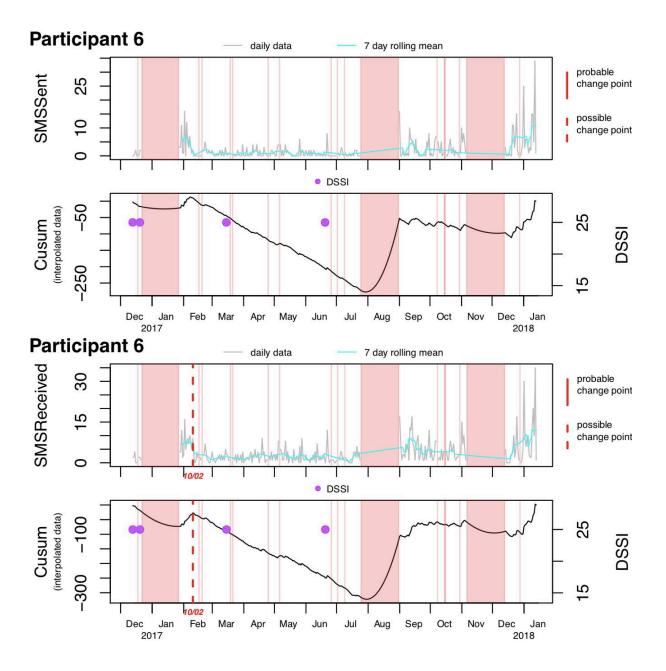


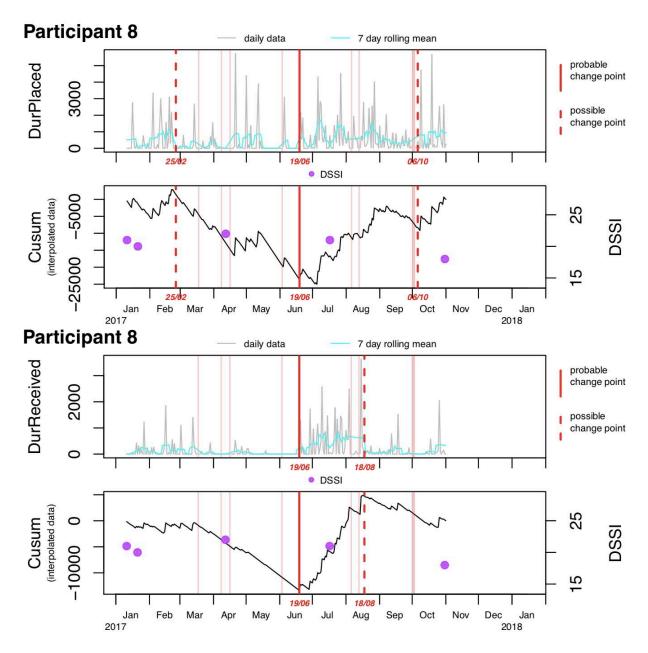




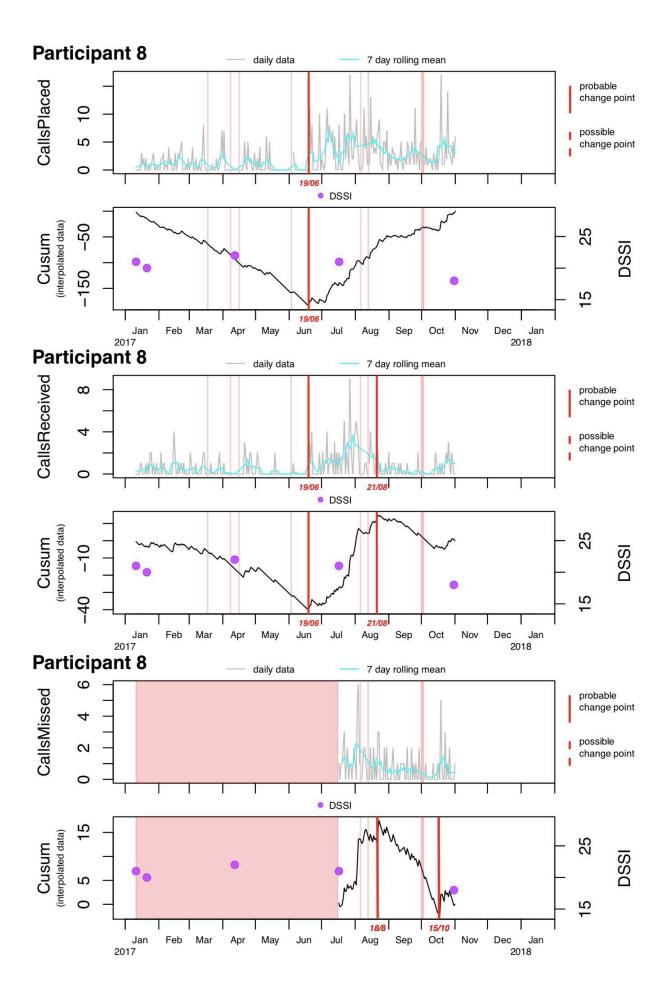


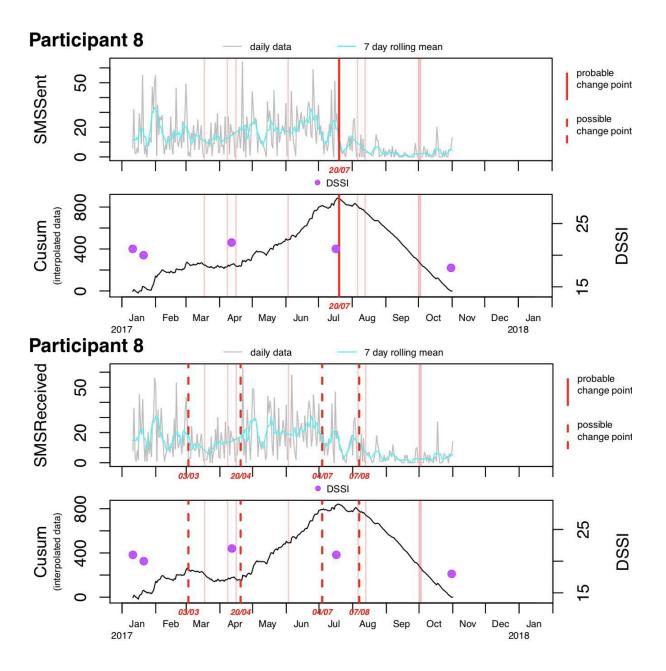


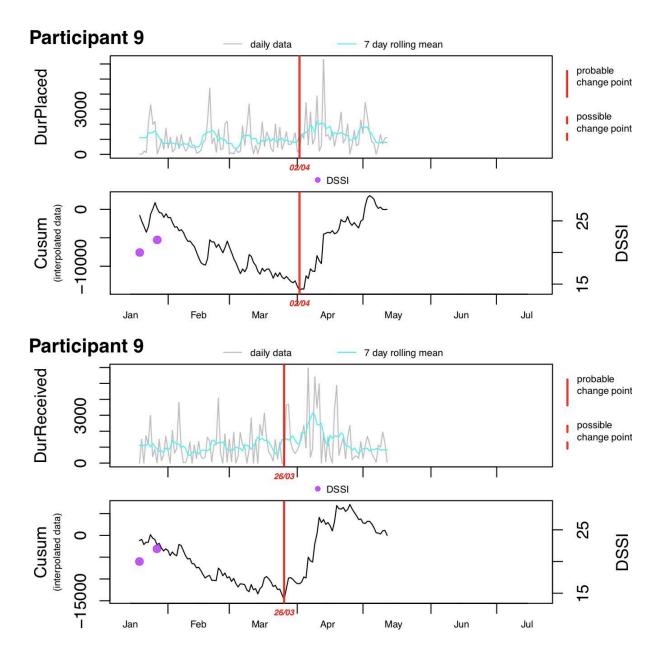


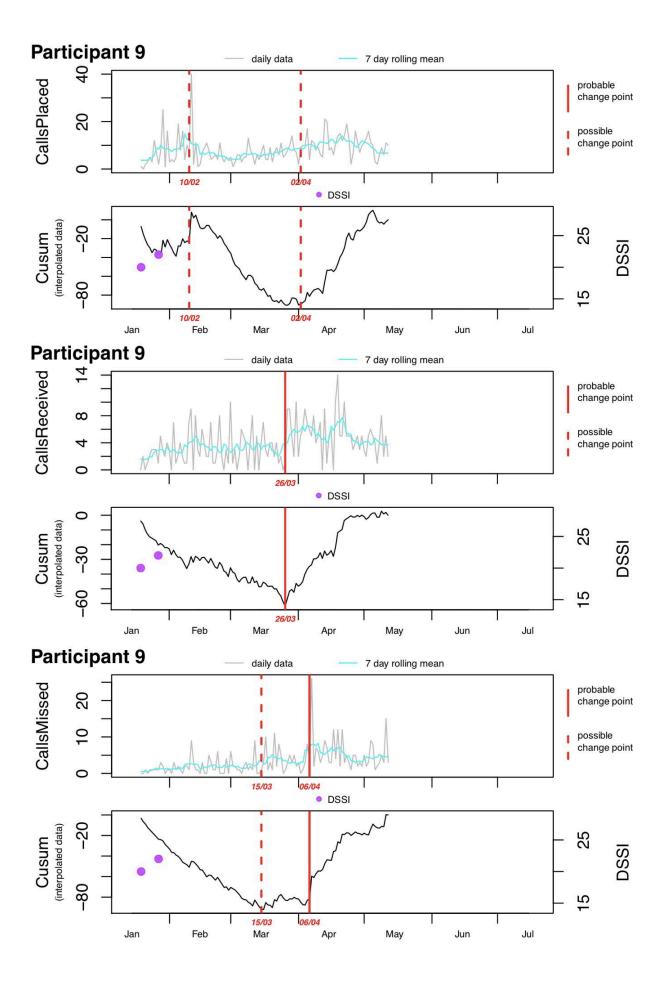


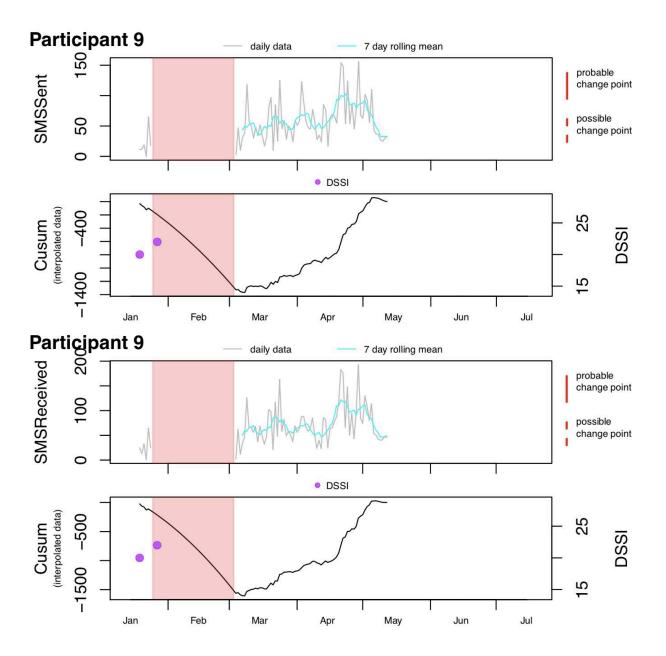
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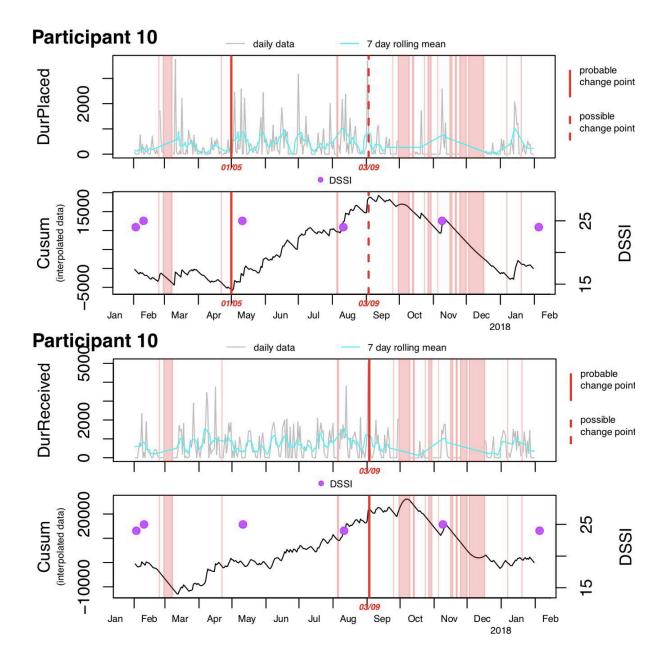


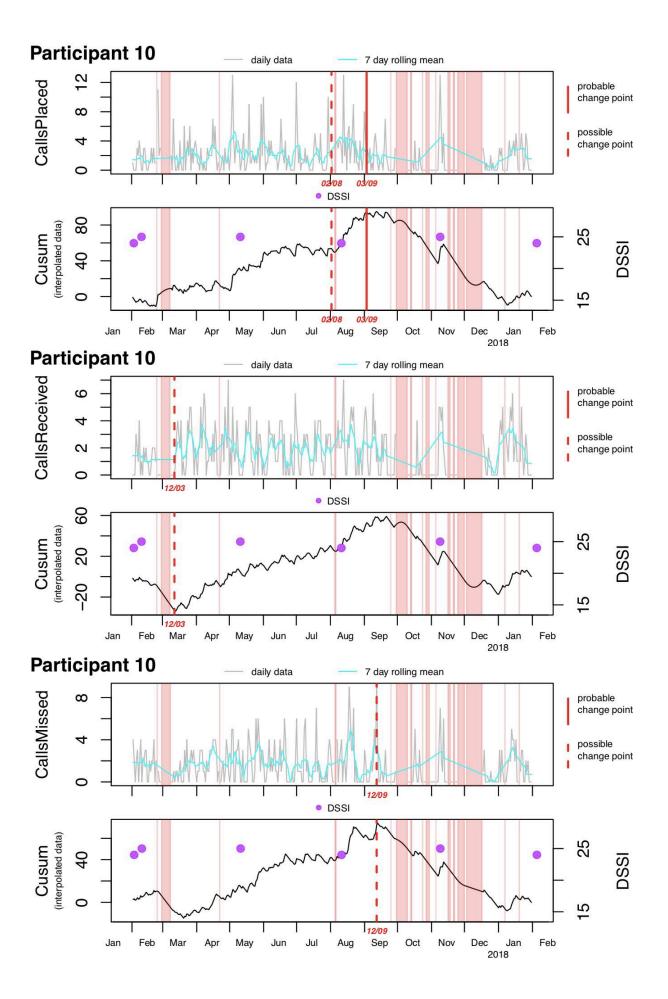


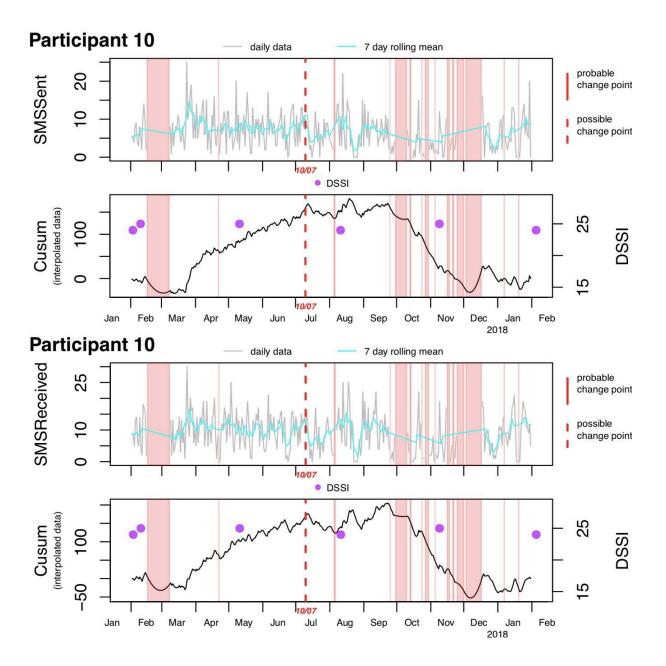


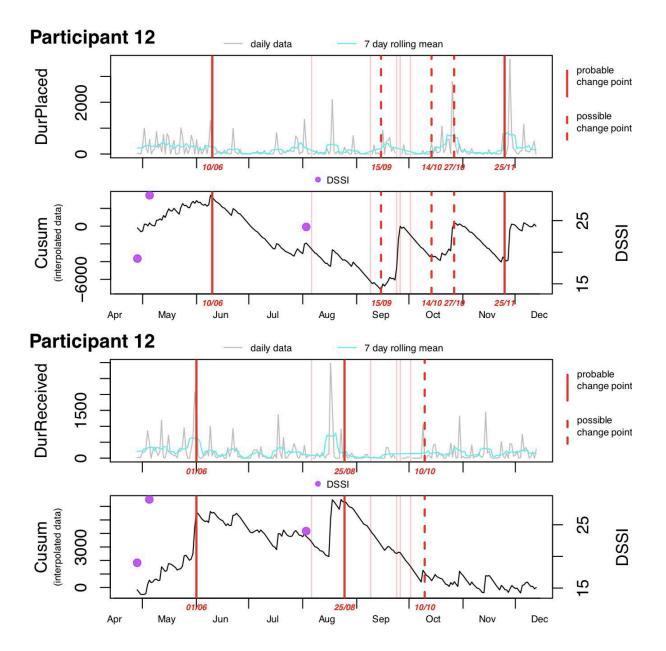


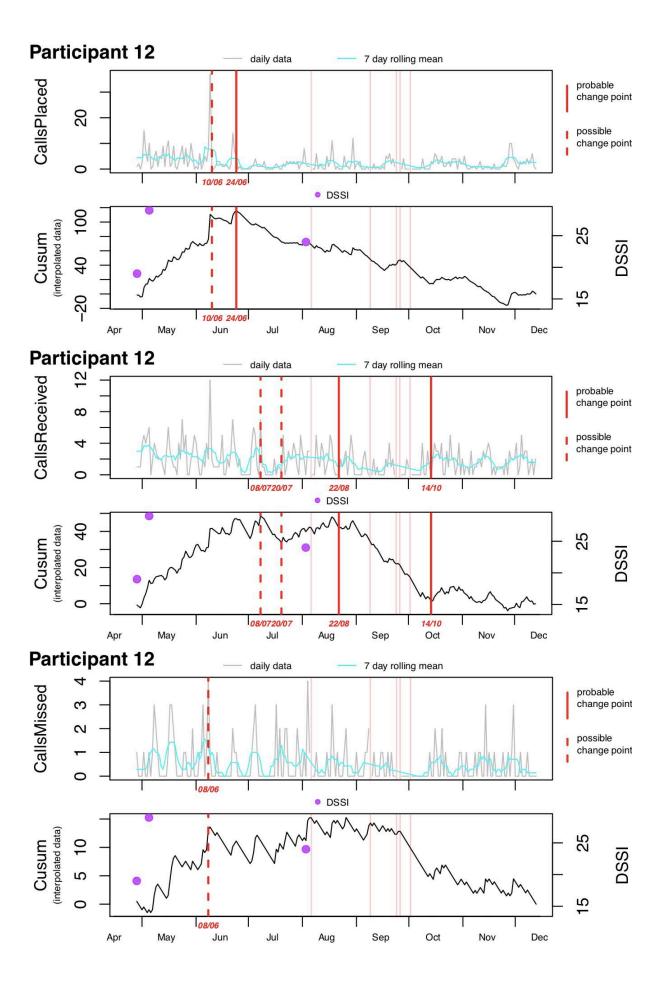


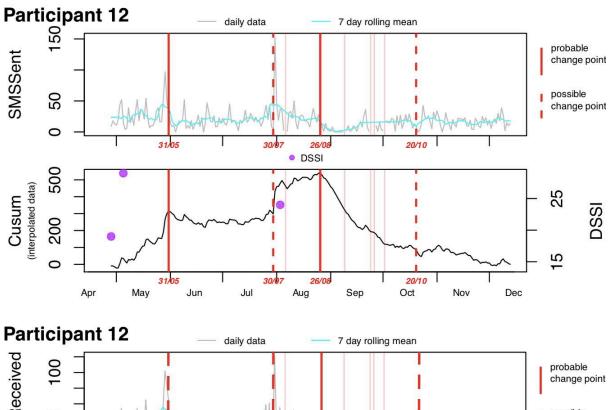


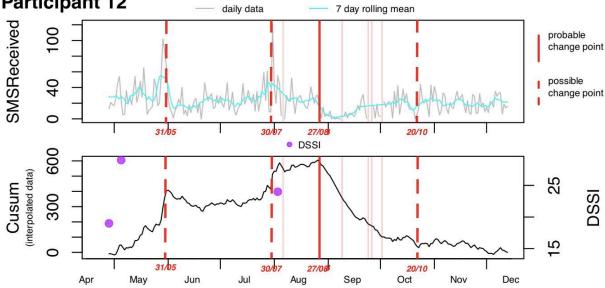




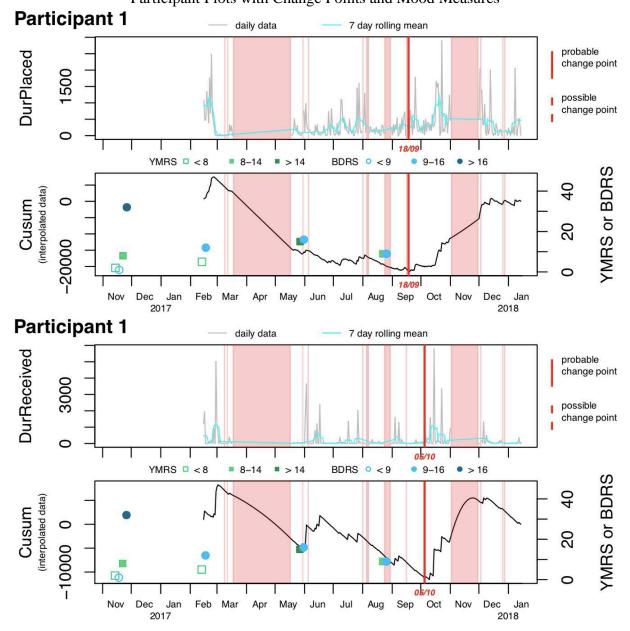








## Appendix O Participant Plots with Change Points and Mood Measures

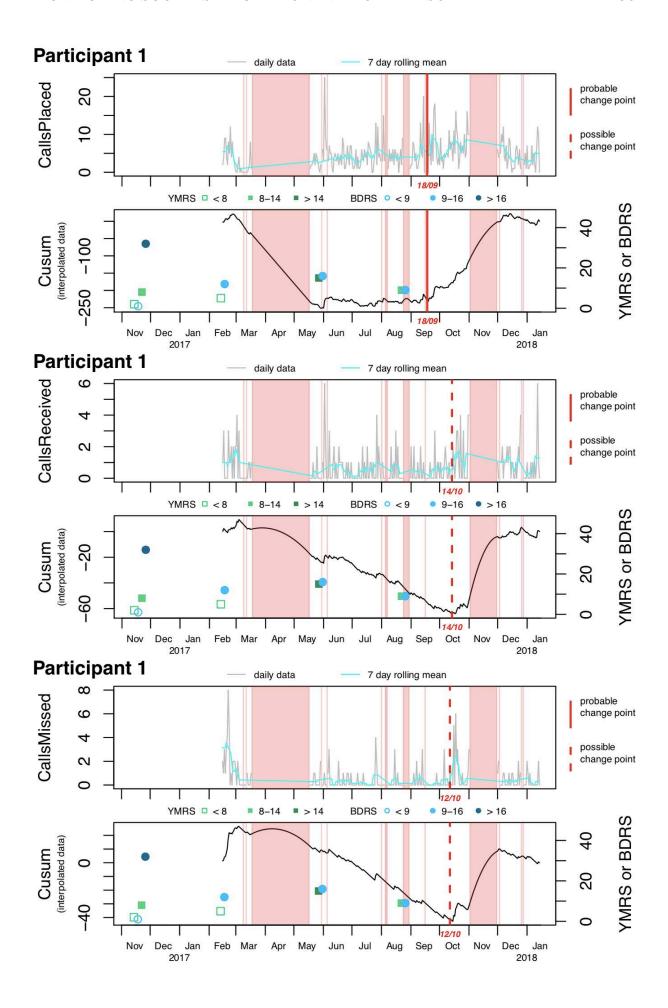


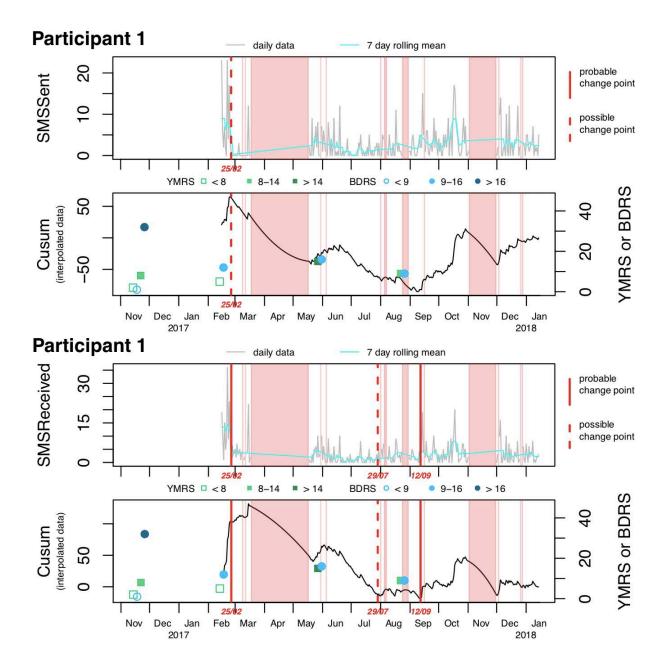
Note. Pink sections represent missing data; Red vertical lines represent change points (CP); Black line and left Y-axis represent CUSUM of data for each variable (DurPlaced = duration of calls placed (in seconds);

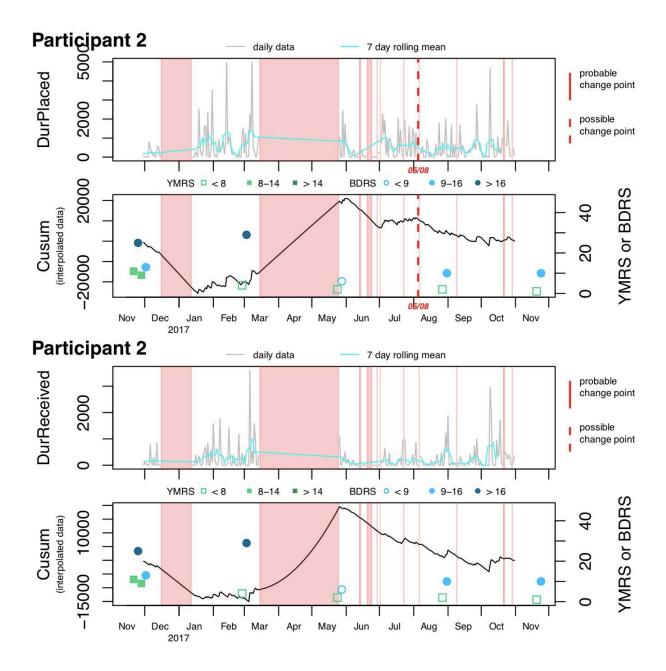
DurReceived = duration of answered calls (in seconds); CallsPlaced = number of calls made; CallsReceived = number of answered calls; CallsMissed = number of unanswered calls; SMSSent = number of SMS sent;

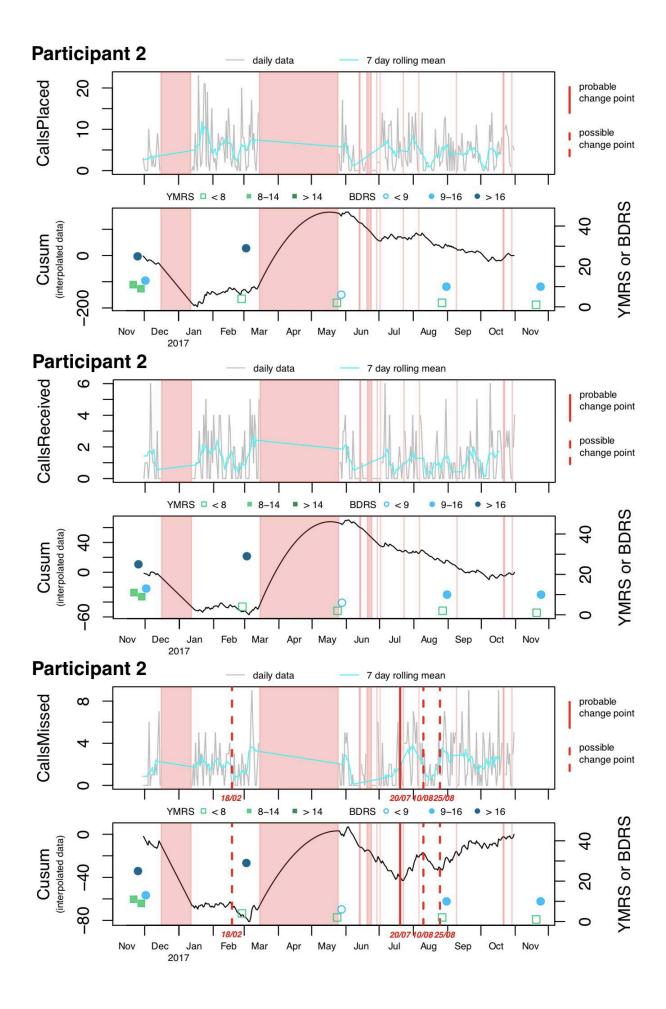
SMSReceived = number of SMS received); Green squares and right Y-axis represent Young Mania Rating

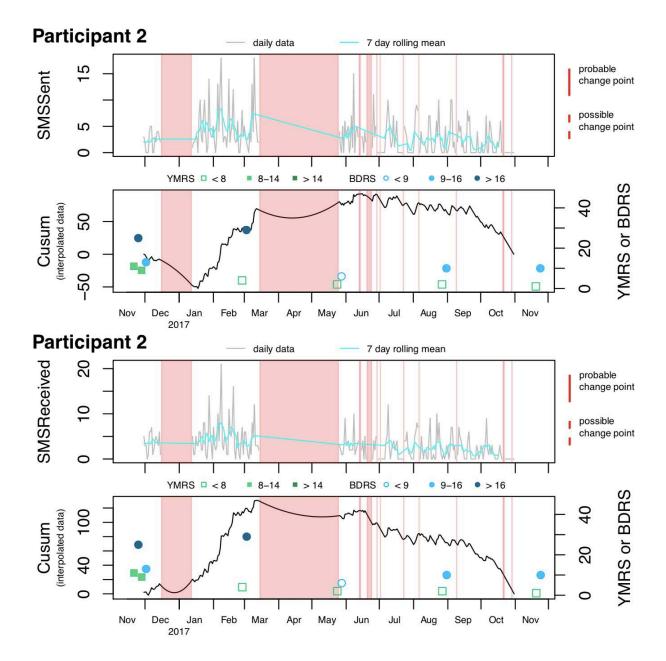
Scale (YMRS) scores (clear square = <8; light green square = 8-14; dark green square= >14); Blue circles and right Y-axis represent Berk Depression Rating Scale (BDRS) scores (clear circle = <9; light blue circle = 9-16; dark blue circle = >16); X-axis represents time since baseline.

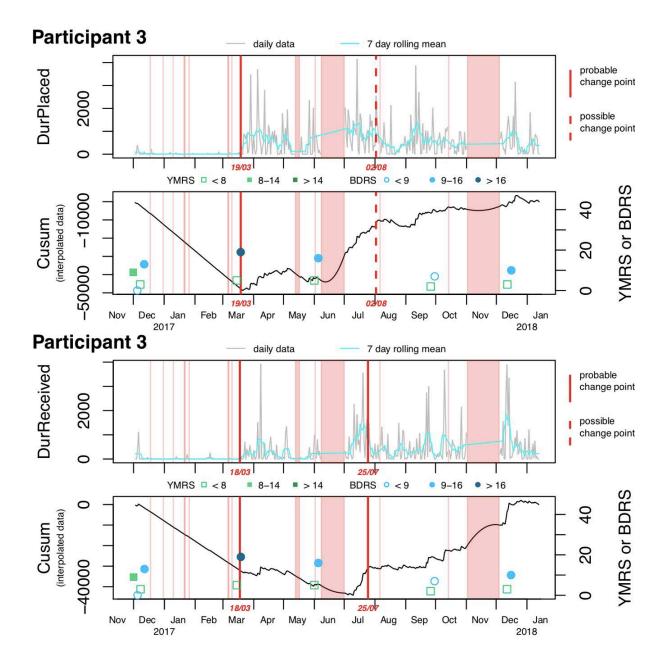


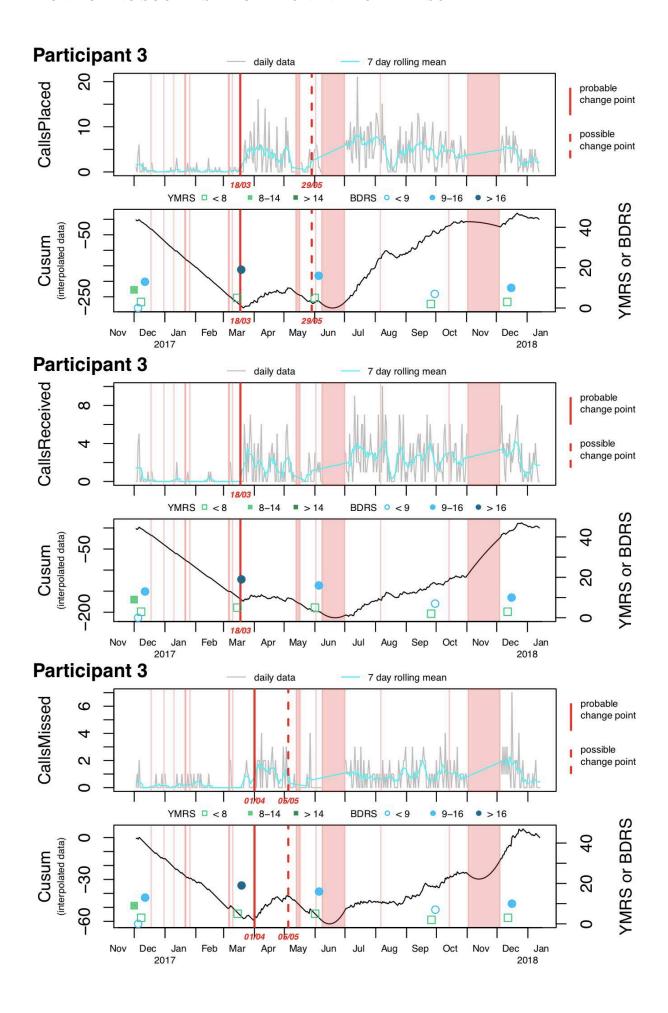


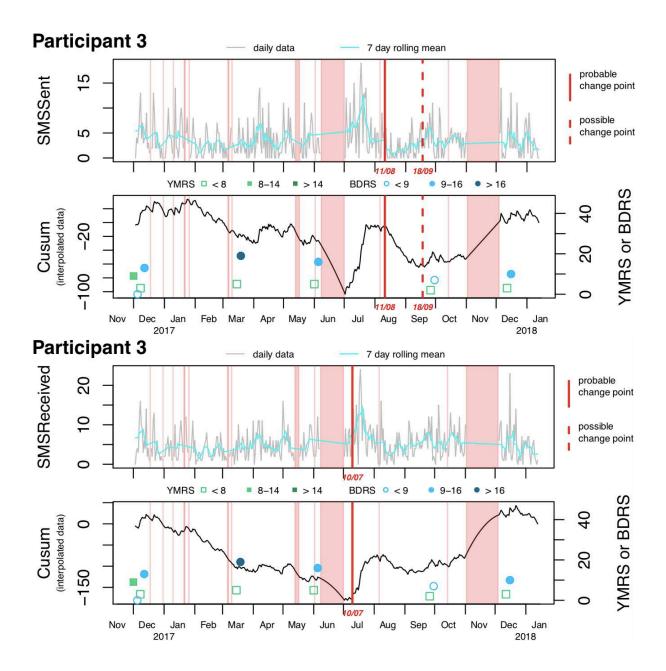


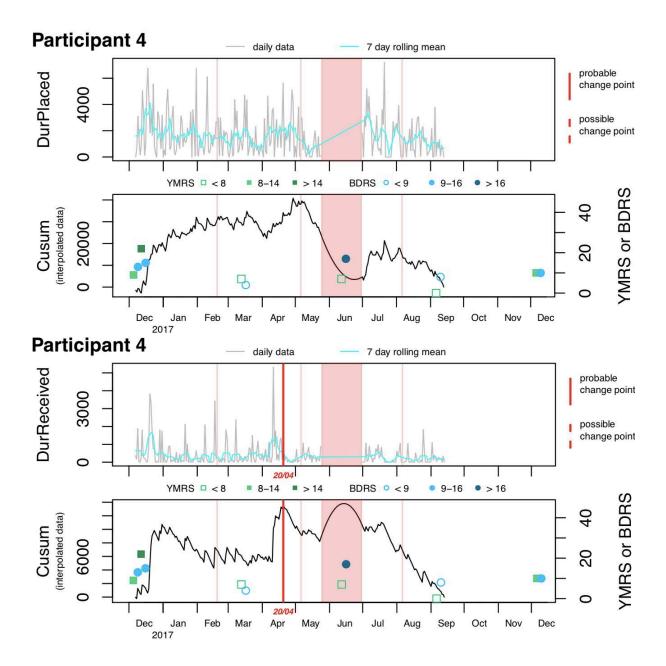


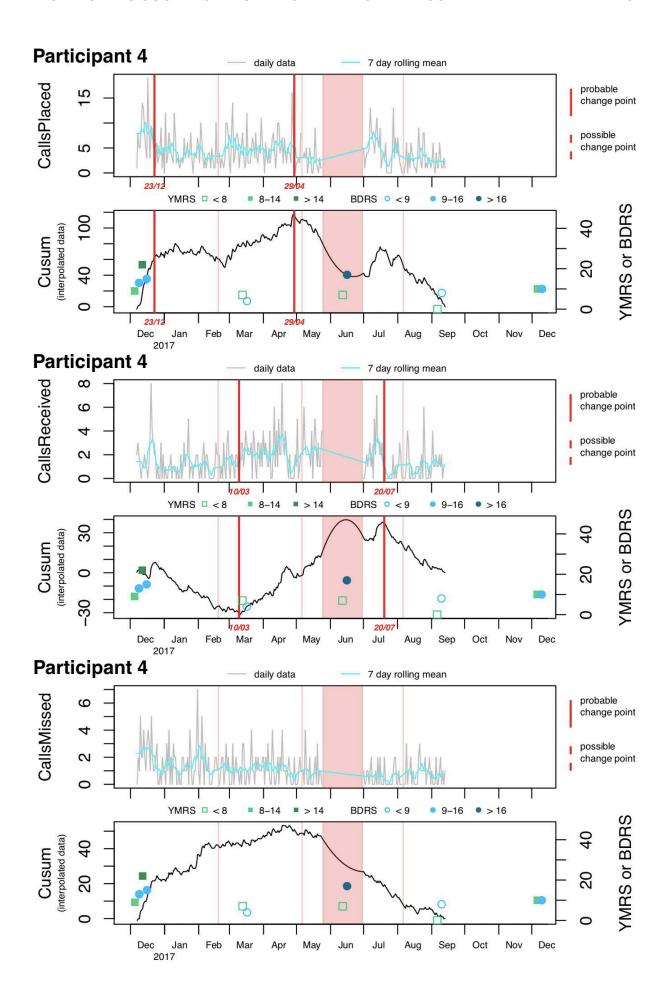


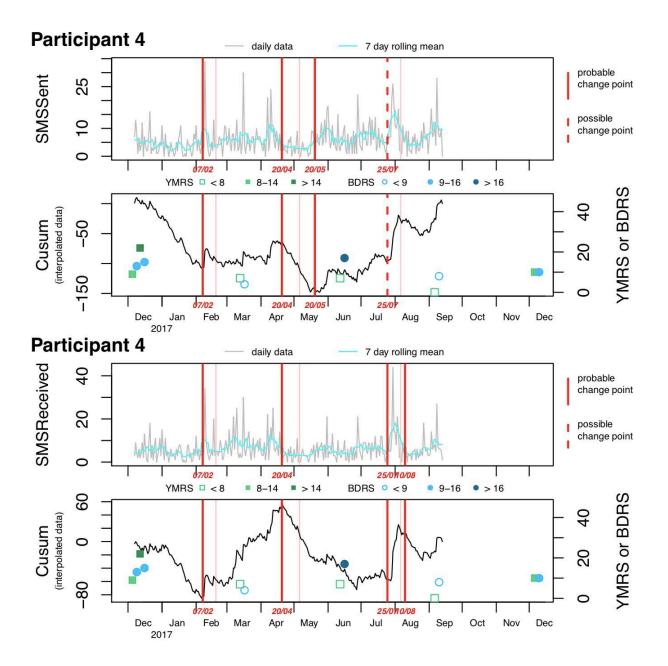


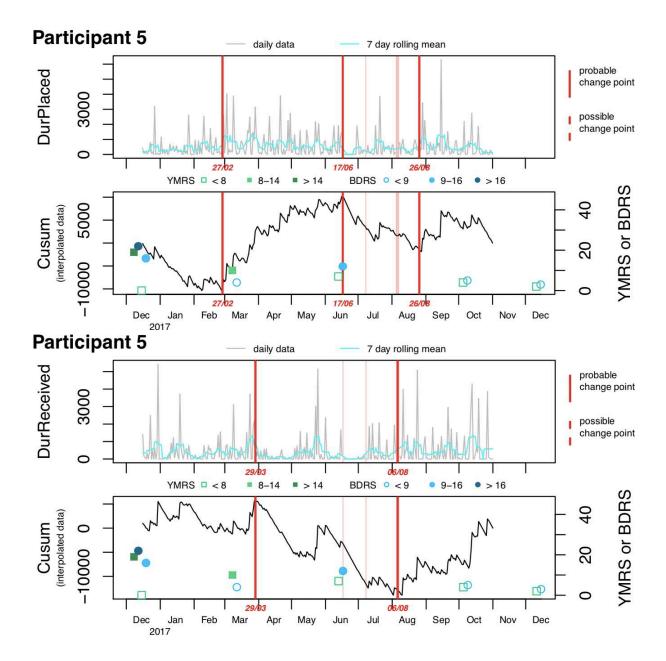


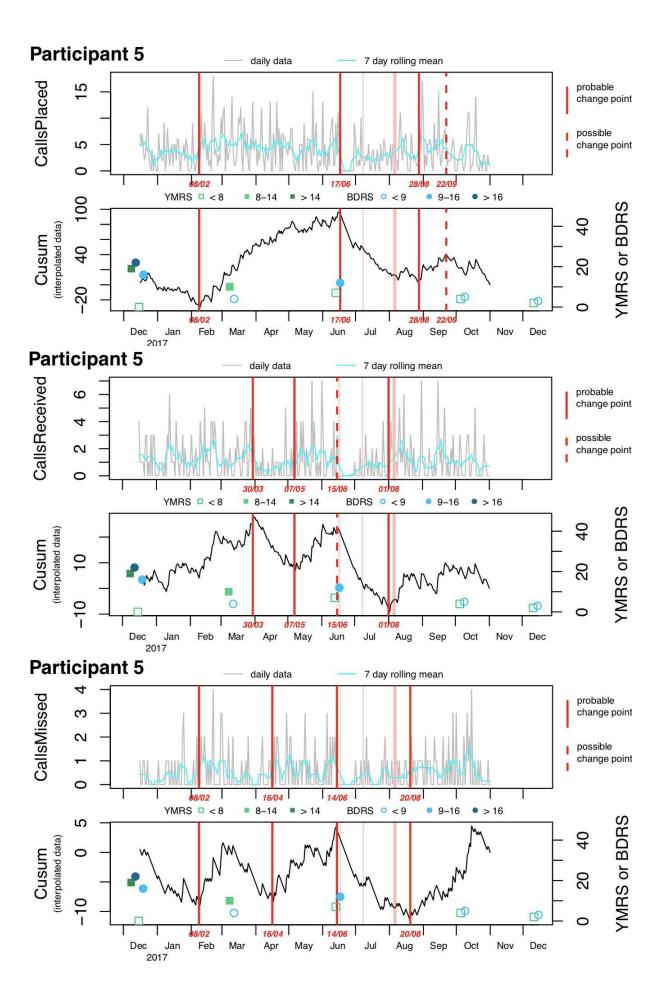


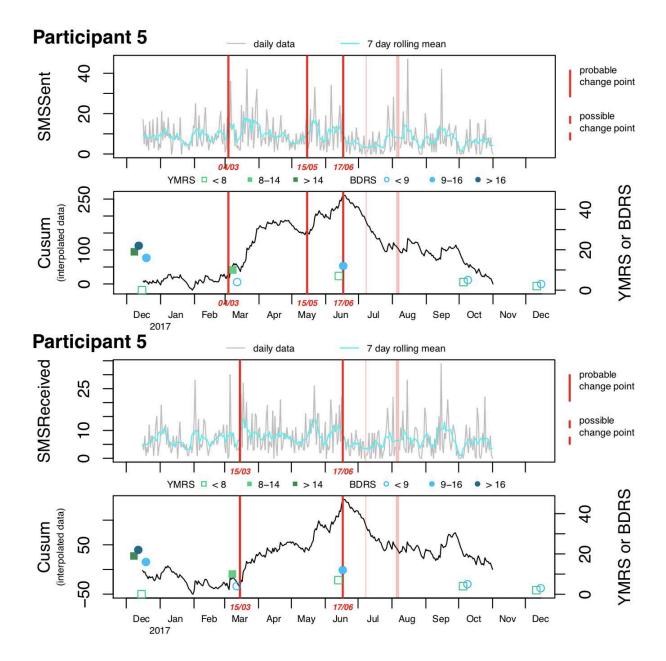


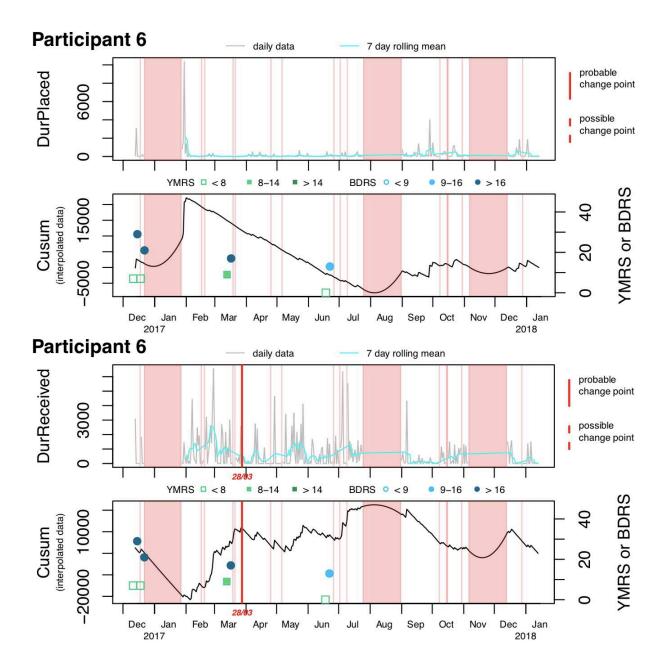


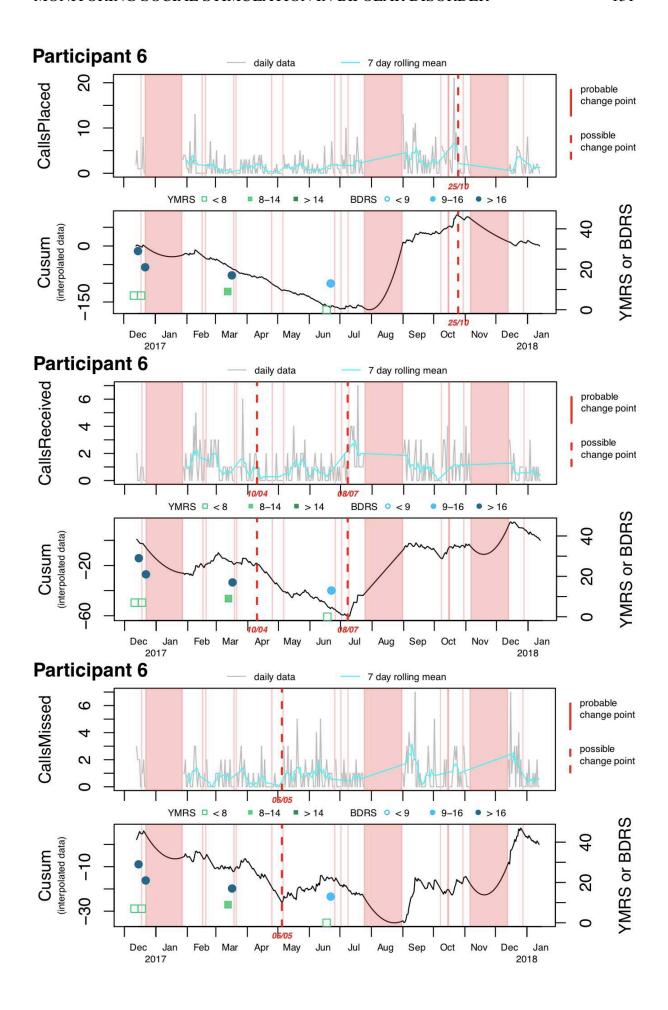


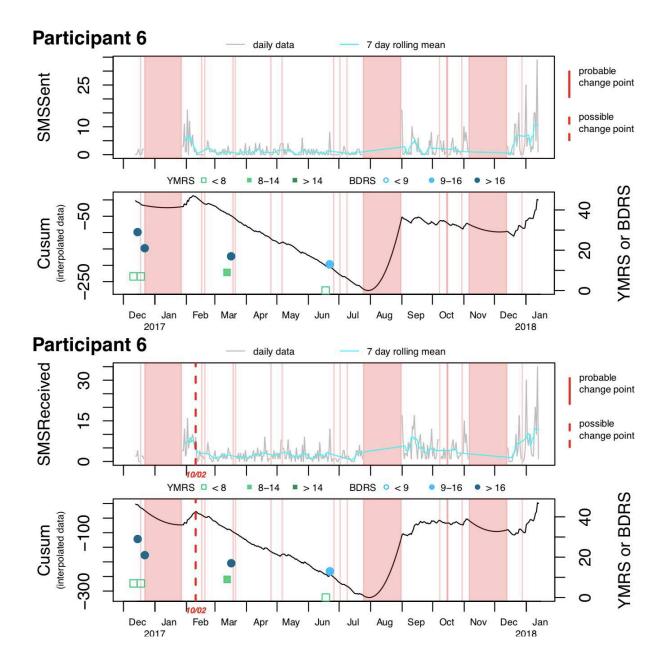


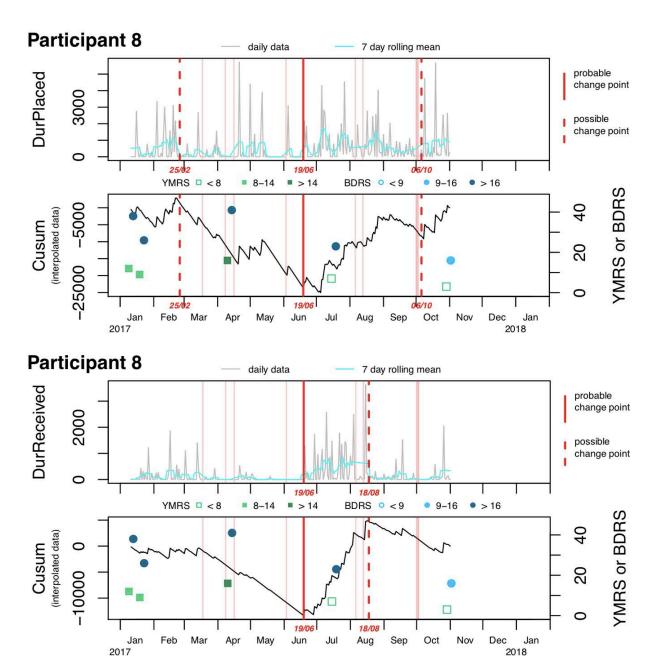


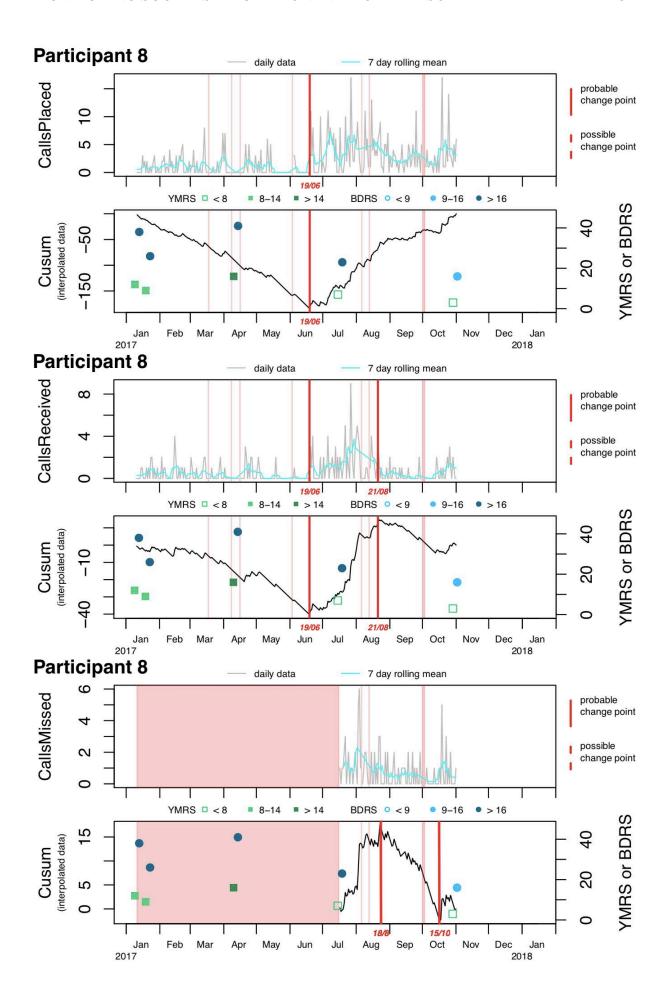


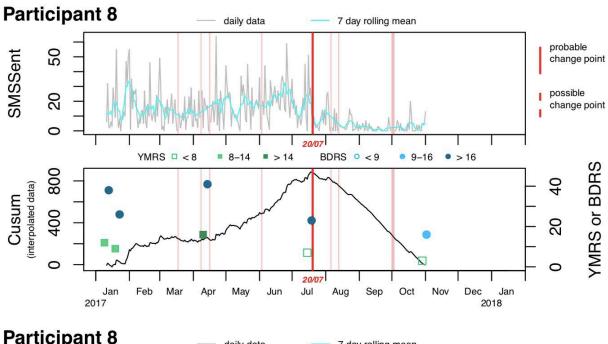


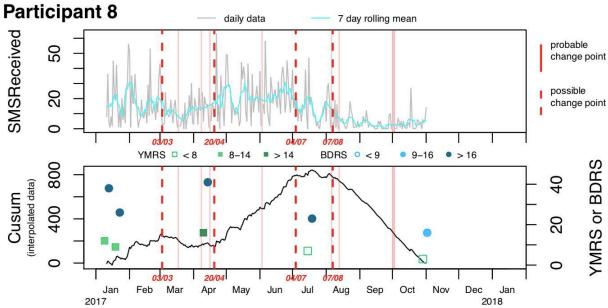


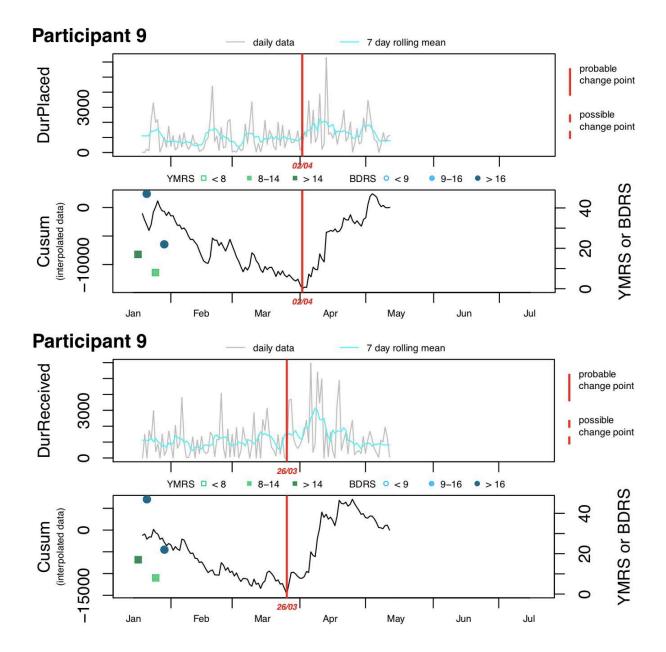


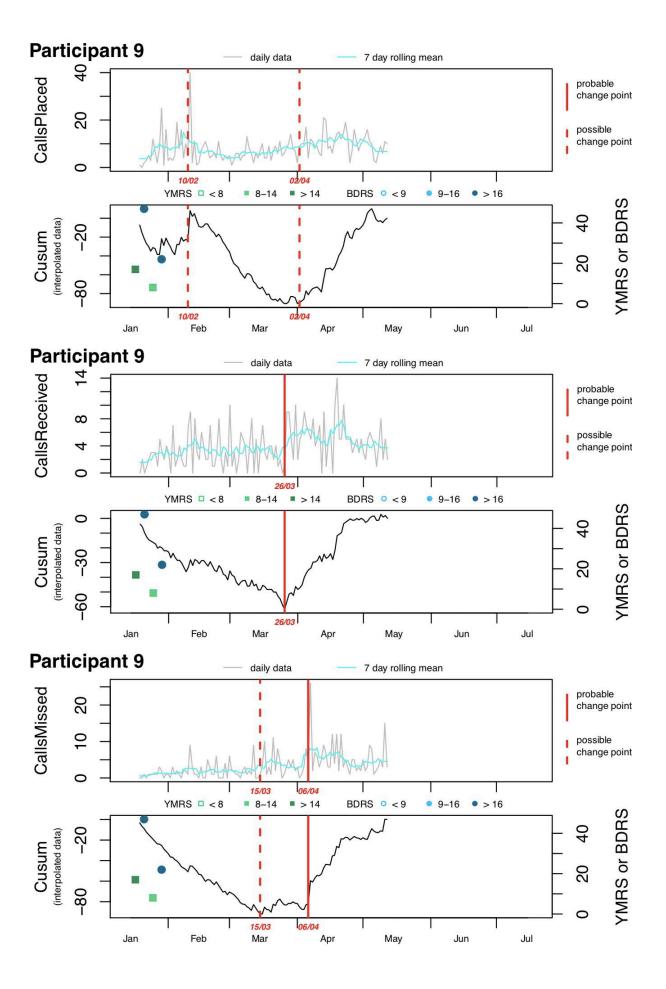


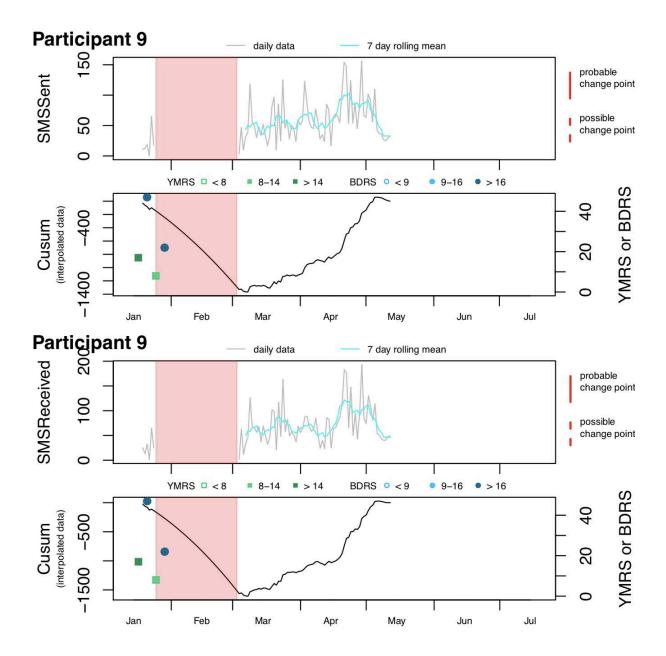


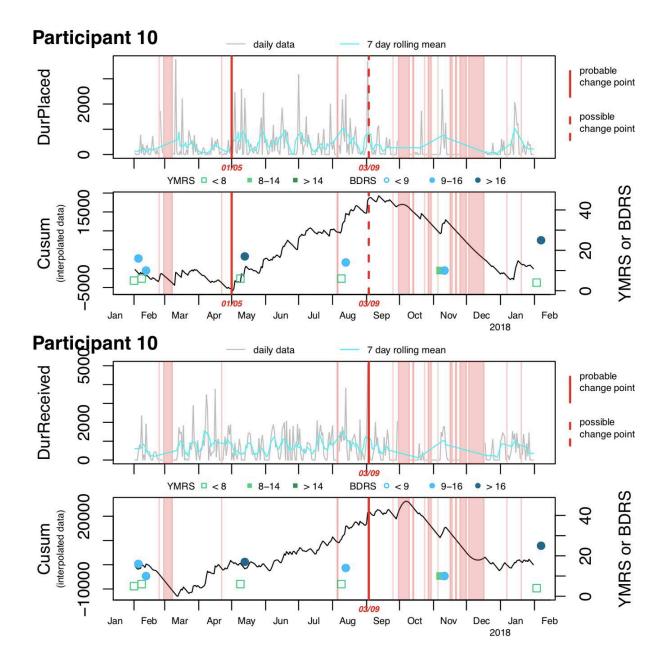


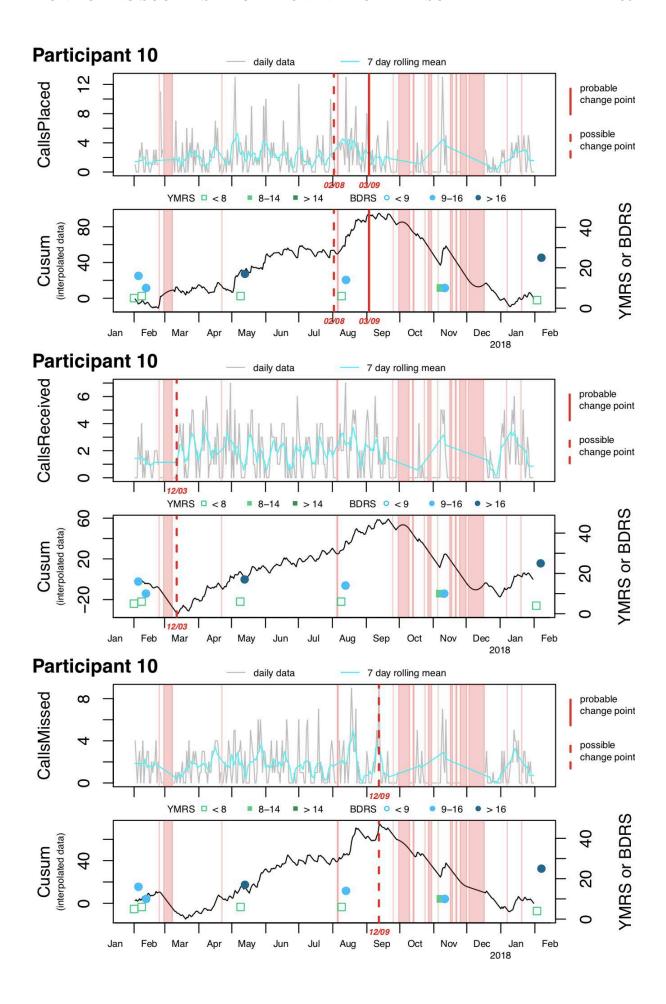


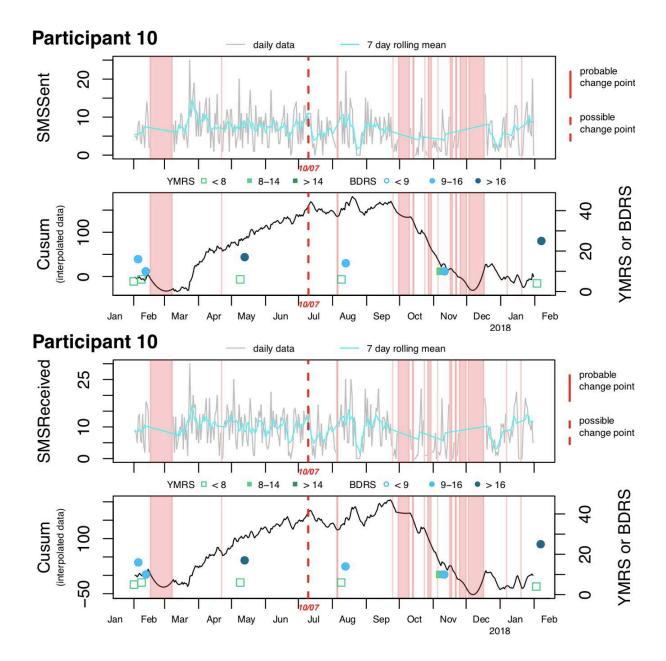


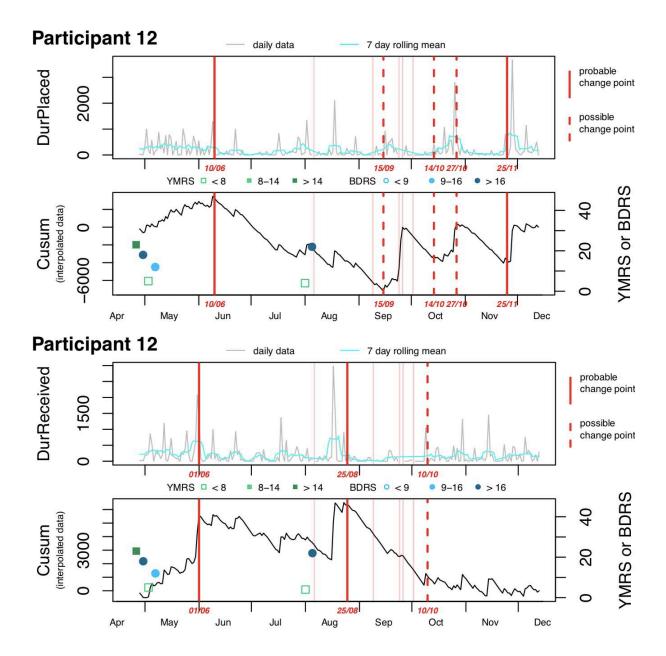


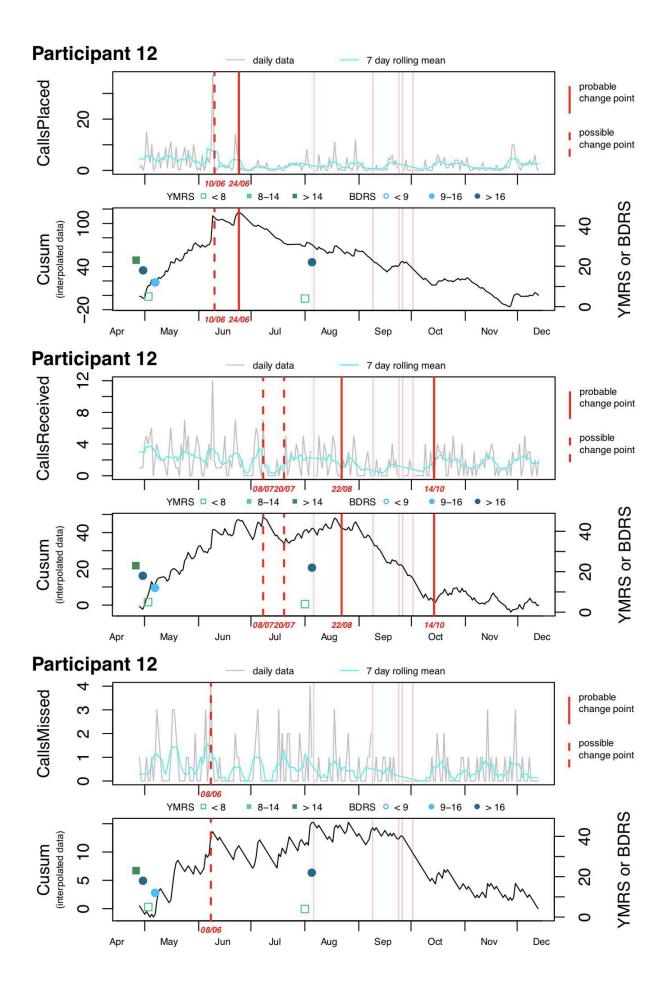


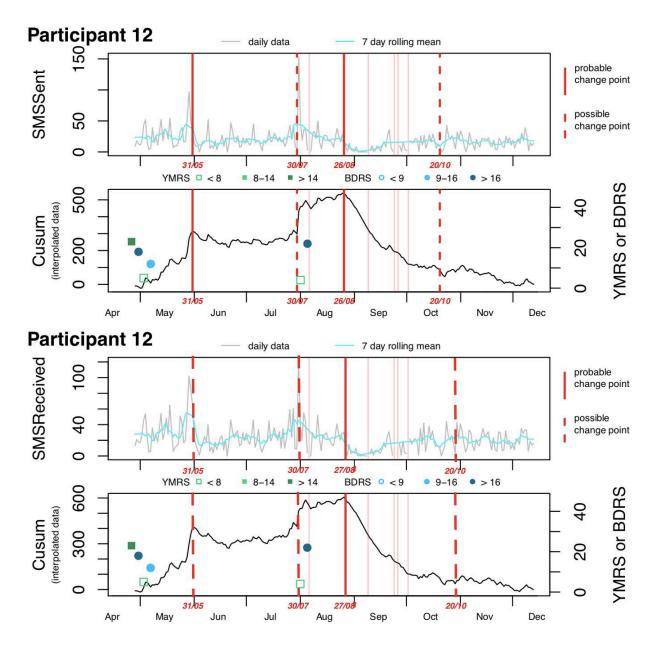












Appendix P

#### Corresponding Clinical Contextual Information

× × × 9 (Aug24) 9 (Aug24) 25 (Aug24) 12 (Feb15) × 24 (Feb15) 5 (Feb15) CallsReceived SMSReceived DurReceived CallsMissed CallsPlaced DurPlaced SMSSent YMRS BDRS DSSI

Participant 1 - Summary of Correspondence (Objective Telecommunications Data, Clinical Measures and Clinical Contextual Information)

DEC/2017

NOV/2017

OCT/2017

SEP/2017

AUG/2017

JUL/2017

JUN/2017

MAY/2017

APR/2017

MAR/2017

FEB/2017

Variable

DSSI= score out of 30. YMRS= score out of 60. Note. X = probable change point detected. ?= possible change point detected. BDRS= score out of 60.

#### Clinical Contextual Information (corresponding to these dates, where available)

15th Feb - Mood has been relatively stable. Depressed mood around the 24/11/16 led to an unplanned Psychiatric appointment, no other notable symptoms. Increased Lamotrigine by 50mg, to 200m/day. Had many work stresses at that time.

1st Mar - Moving to (overseas) next week.

24th Aug - Living in a motel in (overseas). Working 50-70 hours/week, has had no sick days. Is using less THC, decreased opportunity due to work commitments. Socialising more with colleagues during cigarette breaks at work, is smoking more during these breaks, up to 8/day (overall increase of 5-10/week). Not sleeping as much due to late finishes/early starts at work.

Participant 2 - Summary of Correspondence (Objective Telecommunications Data, Clinical Measures and Clinical Contextual Information)

Variable	FEB/2017	MAR/2017	APR/2017	MAY/2017	JUN/2017	JUL/2017	MAY/2017 JUN/2017 JUL/2017 AUG/2017	SEP/2017	SEP/2017 OCT/2017 NOV/2017 DEC/2017	NOV/2017	DEC/2017
DurPlaced							٤				
DurReceived											
CallsPlaced											
CallsReceived											
CallsMissed	٤					X	ن ن				
SMSSent											
SMSReceived											
BDRS		29(Mar1)					10 (Aug29)				
YMRS		4 (Mar1)					2 (Aug29)				
DSSI		15(Mar1)					24 (Aug29)				
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DSSI= score out of 30. YMRS= score out of 60. ?= possible change point detected. BDRS= score out of 60. Note. X = probable change point detected.

## Clinical Contextual Information (corresponding to these dates, where available)

15th Feb - Hospitalised overnight 3 days ago.

1st Mar - Mood has been more stable recently than previously. Appears to be in a current MDE. Depressive relapse on Feb13 required police/ambulance and overnight hospitalisation. For 1-2 weeks prior to that experienced depressed mood, fatigue, irritability, nonspecific suicide ideation, worthlessness, paranoia, social anxiety, increased sleep. Has been isolating herself from others. Alcohol induced rage (overdose?) preceded hospitalisation, alcohol also implicated in previous relapses. Ceased Seroquel, commenced Lamotrigine 200mg. 9th Aug - Experienced paranoia/psychosis 3 days ago, believed her husband wanted to harm her. Was able to stay rational enough to discuss it. Stayed home from work, used identified strategies. Was rational again by midday, had recovered by bedtime. Was happy, because paranoid thinking has previously been a precursor to a relapse but able to work through it on this occasion.

29th Aug - Is 14 weeks pregnant and going well. Had a short episode (3-4days) where she worried her baby would be taken away because of her BD symptoms. Husband was able to reassure her, did not require further intervention. Slight hypomania associated with the above but no other symptoms. Is sleeping more during the day due to pregnancy. Is exercising less due to recent iron transfusion.

Participant 3 - Summary of Correspondence (Objective Telecommunications Data, Clinical Measures and Clinical Contextual Information)

Variable	FEB/2017	MAR/2017	APR/2017	MAY/2017	MAY/2017 JUN/2017	JUL/2017	AUG/2017	SEP/2017	OCT/2017		NOV/2017
DurPlaced		×					٤			S 3	
DurReceived		×				×					
CallsPlaced		×		c							
CallsReceived		×						5		£	
CallsMissed			×	ذ		3				(5 - 5	
SMSSent							×	è			
SMSReceived						×					
BDRS	Y.	19(Mar17)		3,20	16(Jun3)			7 (Sep28)		S	
YMRS		5 (Mar17)			(Suns)			2 (Sep28)			
DSSI		19(Mar17)			23(Jun3)			20(Sep28)			

DSSI= score out of 30. BDRS= score out of 60. YMRS= score out of 60. ?= possible change point detected. Note. X = probable change point detected.

### Clinical Contextual Information (corresponding to these dates, where available)

consistently across preceding 3 months. Had not missed any work, no other symptoms. Has been attending couples counselling, frustrated by lack of progress, would like to work it out. Sees Psychiatrist every 4 weeks, is considering seeing a Psychologist for individual work, may suggest changing relationship counsellors. Current job is less 17th Mar - Vertigo has settled, medications maintained at same levels as previous. Only change has been less exercise. Retrospectively reported feeling mildly depressed stressful than previous. Has been exposed to suicide (of colleagues and other), feels he is handling this well.

3rd Jun - Has been going ok. Decreased overtime at work has helped mood stability. Frustrated that mood is restricted but realises more highs also means more lows, feels medication is working ok. Has spoken to Psychiatrist about suicidal thoughts. Sustained an injury while socialising on holidays recently, can't exercise as much due to this. Sleeping enough but not regularly due to shift work. Found UM app was turned off for 2 weeks, has a new phone now.

6th Sep - Between jobs at present.

28th Sep - Received a voluntary redundancy from work a couple of weeks ago, ceased shift work and sleep/wake patterns more regular. Has been attending a CBT group, enjoying this. Mood more even, but still spending money somewhat. Attended a Health retreat recently, ceased caffeine and sugar. No changes in substance use or socialisation.

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Variable	DEC/2016	JAN/2017	FEB/2017	MAR/2017	APR/2017	MAY/2017	JUN/2017	JUL/2017	AUG/2017	SEP/2017
DurPlaced			S N							- 11
DurReceived					×					
CallsPlaced	×				×					
CallsReceived				×				×		
CallsMissed										
SMSSent			×		×	×		è		
SMSReceived			×		×			×	×	
BDRS	15 (14Dec)			4 (15Mar)			17(14Jun)			
YMRS	22 (14Dec)			7 (15Mar)			7 (14Jun)			
DSSI	26 (14Dec)			21(15Mar)			21(14Jun)			

Note. X = probable change point detected. ?= possible change point detected. BDRS= score out of 60. YMRS= score out of 60. DSSI= score out of 30.

#### Clinical Contextual Information (corresponding to these dates, where available)

14th Dec - Increased hypomanic/manic symptoms this past week. Has insight and is enacting management plans. GP reports may be medication related, and has increased Lamotrigine. Is more motivated to exercise and socialise, decreased ability to sleep. 1st Feb - Mood is variable across the day. Reports being forgetful and disorganised, feeling under pressure to fit everything in. Poor sleep with early waking, Valium PRN at night if can't initiate sleep. Other medications stable.

8th Feb - Has been physically ill over the past week, Lamotrigine reduced to 100mg to reduce side effects. Too unwell to notice mood, sleep vastly increased.

15th Mar - Significant mood variability, mild depressive and the mixed episodes (approx. 1 month apart). Each episode lasted 5-7 days. Depression symptoms included fatigue, pressured speech and agitation. Environmental/psychosocial stressors and medications changes, associated with mood. Appears euthymic at present, reports feeling stable isolation, low mood, decreased appetite, poor concentration, nonspecific suicidal thoughts, worthlessness. Hypomanic symptoms included racing thoughts, decreased sleep, after a recent holiday. Increased smoking to 5-6 cigarettes/day. Sleep cycles are variable, exercise depends on context and socialising depends on mood

12th Apr - Mood is stable at present. Partner in hospital - heart attack 3 days ago. Ceased Epilim, increased Lamotrigine to 200mg without side effects.

19th Apr - Ongoing stressors as a result of partners illness. Some forgetfulness.

26th Apr -Mood is more controlled, medication working well.

14th Jun - Mood is more stable, some mild elevation but no mania. Has had some mixed mood at times, only lasting 1-2 days. Ceased smoking 6 weeks ago, no other changes 20th May - Labile mood this week, irritable and teary, arguing with partner has increased. Sleep disrupted for 2-3 days, Valium PRN assisted. Ceased smoking 2 weeks ago.

19th Jul - Interpersonal stressors associated with separation from partner and death of neighbour. Reports mixed emotions, mainly sadness but not depressed.

in substance use, exercise or socialising. Sleep has been disrupted, impacted partner's shift work. Can go for days with no sleep then will have a long sleep.

26th Jul - Mood is stable, but continues to feel sad/grief.

2nd Aug - Mood has been mixed, not appropriate to circumstances. Adjusting to life without partner. Anxious about potential low mood after things settle down.

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DRS			4 (10Mar)		20	12(15Jun)				
MRS			10(10Mar)			7 (15Jun)				
DSSI			20(10Mar)			27(15Jun)	IU			

DSSI= score out of 30 YMRS= score out of 60. Note. X = probable change point detected. ?= possible change point detected. BDRS= score out of 60.

## Clinical Contextual Information (corresponding to these dates, where available)

8th Feb – Is ruminating on interpersonal conflict from previous week. Increased anxiety has interfered with mood over the weekend, symptoms included agitation, anger, irritability, tearful, 1st Feb - Experienced interpersonal stressors, with prominent conflict and loss of a friend. Feeling frustrated and critical of others' inability to manage MH symptoms. elevated. Episode lasted 3 hours, very short cycle compared to previous experiences.

22" Feb – Has been busy with work, anxious about performance and continuing to ruminate on interpersonal conflict.

10" Mar - Has been chronically dysthymic for the preceding 3 months, some periods of racing thoughts and elevated mood. Major interpersonal issues resulted in anxiety, sadness, anger 1st Mar - Sleep has been disrupted. Increased Quetiapine, resulted in poor functioning in mornings. Had been motivated to exercise, is thinking clearly and feeling more positively. and rumination. Has commenced Lurasidone, and mood has improved. Worried this may be an escalation into elevated mood.

29th Mar - Continuing to recover well, taking Endone nightly to alleviate pain in order to sleep. Sleeping in until 10am daily. Has been learning many new crafts, painting, knitting while 22nd Mar - Recovering from surgery. Missed medication dose (uncharacteristic) and became anxious. Sleep had been disrupted but improved last night. Reported feeling optimistic. recuperating. Reported mood is elevated but sustainable.

12th Apr - Continuing to recover well, reports mood has been stable with minimal effort. Sleep is still increased, is feeling rested.

19" Apr - Mood has been flat, with irritability, anxiety and racing thoughts over the past week. Sleep initiation had been poor, but sleep and mood have improved in last 2 days.

18" May - Variable mood, associated with disrupted routines, no exercise and poor sleep initiation. Increased socialising in the past month has impacted alcohol and food habits.

10" May - Sleep is much improved. Reports monitoring and trying to reduce alcohol use, particularly in social situations. Exercise has increased.

Experiencing bad depression for 1-2 weeks (2 weeks ago), second week was really bad. Feels euthymic/slightly hypomanic at present, sustained but functional, Increased Quetiapine to manage depression, has resumed previous dose now. Has ceased alcohol after an accident resulting in physical injury occurred while drinking socially 3 weeks ago. 7th Jun - Has been on annual leave. Currently experiencing an MDE, became aware of onset quicker than usual. Has enacted management strategies and mood is improving.

21st Jun - Experienced interpersonal loss, friend of family, resulting in increased anxiety and sadness/grief. Increased Quetiapine to assist with sleep.

2<sup>nd</sup> Aug – Sleep has been variable recently, difficulties initiating due to agitation. Missed a dose of medication, a rare event.

9th Aug – Sleep is improved and mood is stable. Taking holidays for 2 weeks for another surgery.

23<sup>rd</sup> Aug - Mood is slightly low, and agitated, believes this is associated with painkillers from surgery.

30" Aug - Sleep continues to be disrupted and mood unsettled, associated with Endone use. Increased Quetiapine (to 700mg) to assist with sleep.

20th Sep - Sleep and mood back to normal.

27th Sep - Experienced ANS arousal and reduced sleep. Interpersonal stressors increase anxiety, using Temazepam PRN. Feeling more 'alert' than usual, difficulty making decisions.

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Variable	JAN/2017	FEB/2017	MAR/2017	APR/2017	MAY/2017	JUN/2017	JUL/2017	AUG/2017	SEP/2017	OCT/2017	NOV/2017
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CallsReceived				٤			٤				
CallsMissed					٤						(c)
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SMSReceived		٤									
BDRS			17 (15Mar)			13 (20Jun)					87
YMRS	x 3.		9 (15Mar)			0 (20Jun)					X - 10
DSSI			25 (15Mar)			25 (20Jun)					
Note. X = probable change point detected.	e change point		?= possible change point detected.	point detected.		e out of 60.	BDRS= score out of 60. YMRS= score out of 60.		DSSI= score out of 30.	30.	

#### Clinical Contextual Information (corresponding to these dates, where available)

1st Feb - Has been travelling this week. Is doing yoga daily, and reported mood is more stable and calmer since commencing.

10th Feb - Reported elevated mood associated with interpersonal stressors and responsibilities. Identified interpersonal responsibilities as a trigger for BD symptoms. wellbeing, feels stifled. Had short periods (2 days) of elevated mood in January. Is currently exercising less due to poor motivation. Has been socialising less as has 15th Mar - Is considering seeing a Psychiatrist but uncertain. Is experiencing non-melancholic depression at present, not sad but lethargic, amotivated and angry. Ongoing psychosocial stressors (divorce and house settlement) contribute to her low mood, appears circumstantial. Is responsible for older relative's health and

29th Mar -Mood is stable, is very busy at present. Difficulty with sleep associated with medications, but once asleep is able to sustain.

distanced herself from others who were a negative presence in her life.

12th Apr - Mood is slightly elevated, has been monitoring herself. Is feeling energised and anticipating the settlement of divorce soon.

4th May - Is going on a cruise tomorrow, feeling anxious about being outside her comfort zone. Retrospectively reported having been very irritable across the previous few months.

previously. Has been walking every day, and sleeping more due to increase in quetiapine (100mg increase). Has been socialising less with friends, but more with family, 20th Jun - Ongoing psychosocial stressors continue from previous review. Comorbid PTSD symptoms have been affecting mood. Is taking 5 medications in total now. Reported feeling more in control of mood since recent medications change 6 weeks ago. Anxiety has reduced, reports ongoing mild melancholic mood, not as bad as sometimes weekly. Has set as an alarm to remind her to turn UM app on.

5th Jul - Sustained a physical injury last week, resulting in pain, no exercise and weight gain. Report low mood associated with this. Plans to discuss this with Psychiatrist and Psychologist next week. 13th Jul - Attended planned Psychiatric appointment, discussed options to address ongoing anxiety. Increased Seroquel (to 400mg/day) to combat the elevated mood associated with Lexapro. Has applied for a part time job, looking to increase structure in daily life.

Participant 8 - Summary of Correspondence (Objective Telecommunications Data, Clinical Measures and Clinical Contextual Information)

Variable	FEB/2017	MAR/2017	APR/2017	MAY/2017	JUN/2017	JUL/2017	AUG/2017	SEP/2017	OCT/2017	NOV/2017
DurPlaced	2				×				٤	
DurReceived					×		٤			
CallsPlaced					×					
CallsReceived					×		×			
CallsMissed							×		×	
SMSSent						×				
SMSReceived		ذ	٤			6	٤			
BDRS			23(12Apr)			23(17Jul)				
YMRS			23(12Apr)			7(17Jul)				
DSSI			23(12Apr)			21(17Jul)				
Note. X = probable change point detected. ?= possible change point detected.	e change point	detected. ?=	possible change	point detected.		BDRS= score out of 60.	YMRS= score out of 60.		DSSI= score out of 30.	f 30.

?= possible change point detected. BDRS= score out of 60. YMRS= score out of 60. Note. X = probable change point detected.

# Clinical Contextual Information (corresponding to these dates, where available)

interactions with others and crying frequently. Increased alcohol and nicotine while anxious, is averaging 5 hours sleep/night. Socialising is the same. Bought a new pet Reported a dissociative/panic attack in February. Currently, mood is labile, moving from low to hypomanic. When low, is very sensitive to small triggers, over analysing 12th Apr - Has commenced seeing a Psychiatrist. Diagnoses have been revised, now BD and chronic PTSD from childhood (not BPD). Ceased Pristig, commenced Latuda (40mg), reduced Lamotrigine by 50% due to interaction with Latuda. Is also taking pain medication to manage side effect, as well as Melatonin 4mg/night. and this is helping with mood.

26th Apr - Reported 3 panic attacks in preceding week, associated with workplace stress. Sleep has been disrupted by nightmare on 2 nights during this time.

14th Jun - Is feeling very pressured at work at present.

17th Jul - Reported BD symptoms have settled but anxiety (not trauma related) has increased. Some obsessions and compulsive behaviours reported. Experienced a period of depression immediately following previous assessment, lasting 1 month. Saw Psychiatrist fortnightly around that time. Symptoms responded to an increase in Latuda to 60mg. Is consuming alcohol (1-2 glasses nightly) to calm down after work. Reported being more active due to anxiety but is exercising less

26th Jul - Is preparing to move interstate in the coming week. Anxiety is elevated by the stress of moving.

31st Aug - Has increased Latuda to 80mg/day

Participant 9 - Summary of Correspondence (Objective Telecommunications Data, Clinical Measures and Clinical Contextual Information)

Variable	DEC/2016	JAN/2017	FEB/2017	MAR/2017	APR/2017	MAY/2017	JUN/2017	JUL/2017	AUG/2017
DurPlaced					×				
DurReceived				×					
CallsPlaced			٤		٤				
CallsReceived				×					
CallsMissed				è	×				
SMSSent									
SMSReceived									
BDRS		<b>22</b> (27Jan)							
YMRS		8 (27Jan)							
DSSI		22 (27Jan)							
		l							

DSSI= score out of 30. Note. X = probable change point detected. ?= possible change point detected. BDRS= score out of 60. YMRS= score out of 60.

# Clinical Contextual Information (corresponding to these dates, where available)

27th Jan - Has had 2 panic attacks in the preceding week, and minor depressed mood. Has been socially isolated with son and pets away on holidays.

1st Feb - Parent is unwell, requiring hospitalisation. Mood is variable, is sad and angry about parent's illness.

8th Feb - Has been feeling anxious and down this week.

8th Mar - Parent has been diagnosed with terminal illness. Mood is low this week.

Participant 10 - Summary of Correspondence (Objective Telecommunications Data, Clinical Measures and Clinical Contextual Information)

Variable	JAN/2017	FEB/2017	MAR/2017	APR/2017	APR/2017 MAY/2017	JUN/2017	JUL/2017 AUG/2017	AUG/2017		SEP/2017 OCT/2017 NOV/2017	NOV/2017
DurPlaced					×				٤		
DurReceived									×		
CallsPlaced								ن	×		
CallsReceived			٤								
CallsMissed									٤		
SMSSent							٤				
SMSReceived							ż				
BDRS		10(10Feb)			17(10Feb)			14(11Aug)			
YMRS		6 (10Feb)			6 (10Feb)			6 (11Aug)			
DSSI		25(10Feb)			25(10Feb)			24(11Aug)			

DSSI= score out of 30. YMRS= score out of 60. BDRS= score out of 60. ?= possible change point detected. Note. X = probable change point detected.

# Clinical Contextual Information (corresponding to these dates, where available)

10th Feb - No changes in mood since previous assessment (1 week ago). Consumed alcohol after 13 days of abstinence, is annoyed and spoke to Clinical Psychologist

22nd Feb - Feeling angry and hopeless, premenstrual symptoms noted.

appointments with Clinical Psychologist to monthly. Has increased exercise and is training for half marathon. Sleep is improved. Is struggling with alcohol cravings, attempts 11th May - Mood has been a bit labile, has experienced minor depression for the past month, some thoughts of self-harm but no actions. A recent overseas trip did not affect symptoms. Reported increasing insight about BD, awareness of irrational thoughts and seasonal patterns to low mood. Has decreased time between scheduled to increase time between alcohol use sometimes successful. Has used THC socially a few times.

2<sup>nd</sup> Aug – Mood has been variable, but improving. Feeling more positive.

11th Aug - Mood has been variable. Experienced a low mood episode in May, anhedonia and amotivation but not sad. Minor self-harm at that time. Mood improved since then but still low. Has increased Sertraline to 150mg/day. Not currently suicidal but reported thoughts that she would probably die by suicide in the future. Continuing to reduce alcohol use, and has lost weight. UM is draining phone battery, and using a lot of phone data, now carries a battery pack.

Participant 12 - Summary of Correspondence (Objective Telecommunications Data, Clinical Measures and Clinical Contextual Information)

Variable	APR/2017	MAY/2017	JUN/2017	JUL/2017	AUG/2017	SEP/2017	OCT/2017	NOV/2017	DEC/2017
DurPlaced			×			٤	2 2	2	
DurReceived			×		×		٤		
CallsPlaced			×						
CallsReceived				2 2	×		×		
CallsMissed			٤						
SMSSent		×		è	×		ذ		
SMSReceived					×				
BDRS		12(5May)	× 1		22(3Aug)				
YMRS		5 (5May)			4 (3Aug)				
DSSI		27(5May)			22(3Aug)				

DSSI= score out of 30. YMRS= score out of 60. Note. X = probable change point detected. ?= possible change point detected. BDRS= score out of 60.

#### Clinical Contextual Information (corresponding to these dates, where available)

5th May - Experienced elevated mood for four days last week, increased spending and activity in the garden. Socialised more than usual and had disrupted sleep during that time. Mood is stable now.

31st May - Experiencing depressed mood for the past few days due to interpersonal stressors, lack of social stimulation and inability to exercise this week.

7th Jun - Ongoing low mood but exercise and a new assistance dog is helping to improve mood.

28th Jun - Low mood since last week despite celebrating a birthday on the weekend. Late nights and poor sleep contributing to ongoing low mood. Increased anxiety and struggling to focus after having 2 planned days off work

5th Jul - Feeling amotivated, not exercising due to little energy.

12th Jul - Took 2 days off work due to BD symptoms. Increased anti-depressant medications to assist low mood.

19th Jul - Low mood is lifting, some periods of more elevated mood.

27th Jul - Continued low mood with limited, brief periods of happiness. Difficulties with sleep and lack of exercise noted.

on two occasions. Socialising has reduced as it not exercising as much, is going to sleep later. Phone update has turned UM and IFTT apps off on at least one occasion. hard to focus. Left work early on one occasion due to low mood. Experienced mild depression in May, lasting 4-5 days. Has been having elevated moods for a day or so, months. Has increased Pristiq to 150mg but not noting any improvement. Alcohol intake has increased slightly, 3-4 standard drinks/weekend, and has used THC socially 3rd Aug - Psychologist has taken leave, commenced with a new male counsellor recently. Mood has been mainly depressed, less anxious than previously but finding it previously these would have lasted a week. Elevated mood peaks if socialising, even briefly, and can remain elevated all day. A handful of days across the previous

16th Aug – Mood is stable, no anxiety noted.

24th Aug - Mood remaining stable.

6th Jul - Mood is stable, currently holidaying overseas.

4th Oct - Ceased medications last week, due to side effects. Experienced withdrawal symptoms, bursts of anger and irritability, which is improving.