Title: The Chinese Health Improvement Profile (CHIP) for people with severe mental illness: A Cluster Randomised Controlled Trial

Author details:

Corresponding Author:

Dr Daniel Bressington - Assistant Professor

Mental Health Care Research Group,

School of Nursing, The Hong Kong Polytechnic University, Hung Hom, Kowloon, Hong Kong. HKSAR

Tel: +852 2766 6408

Dan.bressington@polyu.edu.hk.

Co-authors:

Prof Wai Tong Chien – Professor and Associate Head

Mental Health Care Research Group,

School of Nursing, The Hong Kong Polytechnic University

Ms Jolene Mui – General Manger (Nursing)

Castle Peak and Siu Lam Hospitals, Hong Kong

Miss Kar Kei Claire Lam – Research Associate,

Mental Health Care Research Group,

School of Nursing, The Hong Kong Polytechnic University

Dr Ziyad Mahfoud – Associate Professor,

Department of Health Policy and Research,

Weill Cornell Medicine, Qatar

Dr Jacquie White – Associate Dean

Faculty of Health and Social Care,

University of Hull, Hull, UK.

Prof Richard Gray - Professor of Clinical Nursing

College of Science, Health and Engineering,

La Trobe University, Melbourne, Australia.

Authorship:

All authors listed meet the authorship criteria according to the latest guidelines of the International Committee of Medical Journal Editors, and all authors are in agreement with the manuscript.

Acknowledgments:

The study was funded by a professorial start-up grant awarded to the first author by The Hong Kong Polytechnic University. We would like to thank the service user and nurse participants for taking part in the study.

Disclosure:

The authors do not have any actual or potential conflicts of interest.

The Chinese Health Improvement Profile (CHIP) for people with severe mental illness: A Cluster Randomised Controlled Trial

Abstract

This study aimed to establish the feasibility of conducting a full-scale trial and estimate the preliminary effect of a Chinese Health Improvement Profile (CHIP) intervention on self-reported physical well-being of people with Severe Mental Illness (SMI). The study used a parallel group, open label, cluster-randomised controlled trial design. 12 Community Psychiatric Nurses (CPNs) and their corresponding 137 patients with SMI were randomised into the CHIP or treatment-as-usual (TAU) groups. After training the CPNs completed the CHIP at baseline and 12 months and the findings were used to devise an individualised care plan to promote health-behaviour change. Patients were assessed at baseline, 6 and 12 months after starting the intervention. There was an observed positive trend of improvement on the physical component subscale (PCS-12) of SF12v2 in the CHIP group compared to the TAU group after 12 months, but the difference did not reach statistical significance (p=0.138). The mental component subscale (MCS-12) showed a similar positive trend (p=0.077). CHIP participants were more satisfied with their physical healthcare than TAU patients (p=0.009) and the CPNs were positive about the usefulness/acceptability of the intervention. There were significant within-group improvements in the total numbers of physical health risks as indicated by the CHIP items (p=.005). The findings suggest that it is feasible to conduct a full-scale RCT of the CHIP in future. The CHIP is an intervention that can be used within routine CPN practice and could result in small-modest improvements in the physical well-being of people with SMI.

Trial registration:

Clinicaltrials.gov reference number NCT02453217

Keywords:

Physical Health; Severe Mental Illness; SF12v2; Chinese Health Improvement Profile.

Introduction

People with severe and enduring mental illness (SMI) have an elevated risk of developing physical health problems which contribute towards high mortality rates (DeHert, et al., 2011; Brown, Inskip and Barraclough, 2000; Chesney et al. 2014). It has been estimated that people diagnosed with a SMI die between 10 and 30 years earlier than the general population (DeHert et al. 2011; Happell et al., 2011; Walker et al. 2015). The most common physical health problems that have been associated with SMI are cardiovascular disease, metabolic disorders, obesity, some cancers, and respiratory conditions (Robson and Gray, 2007; Vancampfort et al. 2015; Gardner-Sood et al. 2015). The majority of premature deaths in this patient group are attributed to cardiovascular diseases (CVD) (McEvoy et al., 2005; Lawrence et al. 2013).

In response researchers have conducted trials focused on reducing the cardiometabolic health risks of people with SMI. Many studies have aimed to change health behaviours (e.g. physical activity or diet) in order to reduce CVD risk factors such as obesity (Buka, 2008; Ellis et al., 2007; Saxena et al., 2005; Rosenbaum et al. 2014; Firth et al., 2015). Two systematic reviews of intervention studies that aim to improve physical health in SMI (Happell, Davies and Scott, 2012; Soundy et al. 2014) concluded that interventions may result in significant benefits for health behaviours and cardiometabolic health; including improvements in diet, alcohol use, exercise, smoking and weight management but the effect sizes were small.

Regular physical health monitoring for people with SMI is recommended in the National Clinical Guidelines of many countries (American Psychiatric Association, 2004; Department of Health, 2016; National Institute for Health and Care Excellence, 2014). There is some preliminary evidence that lifestyle intervention programmes which comprehensively assess lifestyle behaviours and physical health can help to inform patient-centred care planning and subsequently result in the improved health behaviours of patients with SMI (Ohlsen et al., 2005; Eldridge et al., 2011; White et al, 2009; Bressington et al., 2014). Similarly, Van Meijel et al (2014) reported that a "traffic light method" of conducting a health check (where areas of risk are highlighted as red lights) resulted in statistically significant reductions in the mean waist circumference measurement and weight of people with SMI. The Health Improvement Profile (HIP; White, Gray and Jones, 2009) is intended for use by psychiatric nurses to assess areas of potential health risks e.g. levels of physical activity, lipid and blood glucose levels, quality of diet, oral health. The authors then recommend developing with the patient an individualised physical health care plan, utilising motivational interviewing approaches to promote behaviour change during regular routine clinical meetings. This approach is also supported by the findings of some studies that have used educational approaches and motivational interviewing as a part of an intervention package with SMI patients and which have resulted in significant improvements in levels of understanding about nutrition/exercise (Wirshing et al., 2006), reductions in body weight (mean weight loss of 2.7 kg) (Veerland et al., 2003) and clinically significant reduction in cardiovascular risk (Bartels et al., 2013).

This study builds on our previous work in this area. We reported a prospective case series using the HIP in 148 patients in Hong Kong (Bressington et al., 2014). Over twelve months we observed significant increases in participants' self-reported amounts of exercise (19 participants increased their levels of exercise to recommended limits). We also completed a quasi-experimental before-and-after study of the HIP in 105 SMI patients in Thailand (Meepring et al., 2016). We observed improvements in Body Mass Index (-0.78 kg/m2, p<.001), with 23 patients (22%) shifting to a healthier Body Mass Index classification at one-year follow-up. There were also significant improvements in the total number of "red-flagged" HIP items (p<.001). The HIP intervention and tool was modified for use in Hong Kong based on our previous research findings (Bressington et al., 2014; 2016) to develop the Chinese Health Improvement Profile (CHIP), which is tested in this pilot cluster RCT. The modifications included translation into Chinese language, revisions to supporting/educational materials, terminology changes and the introduction of a "traffic-light" warning system to highlight the health relevance of findings for all individual CHIP items.

Study aims

The main aims of this study were to estimate the preliminary effect size of the CHIP on the perceived physical well-being of people with SMI and establish the feasibility of conducting a full-scale trial.

Primary objective:

- To determine the preliminary effect size of the CHIP on the perceived physical well-being of patients with severe mental illness at 6 and 12-months after intervention commencement compared to treatment as usual (TAU).

Secondary objectives:

- To determine if, compared to TAU, the CHIP enhances perceived mental well-being at 6 and 12 months after the intervention started.
- To establish changes in health behaviours and physical health risks within the intervention group between baseline and at 12 months.
- To establish differences in the objective physical health state of patients between the two groups at 12 months as indicated by data routinely recorded in medical/outpatient/nursing notes during the study duration.
- To determine if, compared to TAU, the CHIP participants were more satisfied with their physical health care at 12 months.

- To ascertain CPNs perspectives about the perceived acceptability and usefulness of the CHIP intervention at 12 months.

Design:

This pilot study used a parallel group, open label, clustered randomised controlled trial design. Community Psychiatric Nurses (CPNs) and their corresponding randomly selected eligible patients were randomised into either the CHIP or TAU group after all baseline measures were completed. The CPNs in the intervention group received one-day CHIP training after random allocation and were instructed to complete the CHIP at baseline and again after 12 months. Patients' outcomes were assessed at baseline, 6 and 12 months. The trial protocol was registered with Clinicaltrials.gov (NCT02453217) before the study commenced. We have carefully followed CONSORT when reporting the findings from this pilot trial.

Study setting:

The study was carried out in a Community Psychiatric Nursing Service in Hong Kong between July 2015 and October 2016. The multi-disciplinary psychiatric service is attached to a large psychiatric hospital in the New Territories and provides community mental health services for the local population of approximately 1.1 million people.

Ethical considerations

Ethical approvals for the study were obtained from the University's Research Ethics Committee (reference: HSEARS20141202001) and the Hong Kong Hospital Authority Cluster Clinical Research Ethics Committee (reference: NTWC/CREC/15007). Patient participants were given written information and allowed at least a day to consider their decision. All participants provided their written informed consent to take part in the study and patients were additionally asked for their permission for their medical notes to be reviewed. All participants were informed that they were entitled to withdraw from the study at any time without having to give a reason, and without negative consequences.

Recruitment:

The lead clinician of the participating community mental health team was asked to nominate CPNs who met the study inclusion criteria. After discussions with the clinical team leader we decided that we would aim for 12 CPNs to take part in the study. This decision was made because approximately 140 participants would be required for detecting a medium-large effect on perceived physical well-being and we aimed to ensure that each CPN participant had a manageable additional workload (i.e. each using the HIP intervention with less than 15 patients). A research assistant visited the CPNs who expressed an interest in participating to explain the study, provide any required additional written information and obtain informed consent.

The consenting CPNs case lists were screened by the clinical team leader to identify potentially eligible patients. All eligible patients from each CPNs list were given a unique number based on the alphabetical order of their surname. An online programme (researchrandomiser.org) was used to generate a separate set of 15 random numbers corresponding to individual patients on each CPN's case list. These numbers were used to determine which patients were approached for informed written consent to take part in the study and each CPN met with these randomly selected patients in numerical order until a minimum of 12 had agreed to take part. Baseline data collection was then carried out with the consenting patients.

Random treatment allocation

After patient recruitment and baseline data collection were completed the CPNs (and their corresponding patients) were randomly allocated to either the CHIP or TAU group. The random treatment allocation was conducted by an external researcher with an online system (sealedenvelope.com) using random permuted blocks to ensure balanced group numbers. [See figure 1 for CONSORT diagram summary of trial design]

Inclusion criteria (CPNs)

Male or female, registered psychiatric nurses with a minimum of 5 years' post-qualification experience working with community-dwelling SMI patients in Hong Kong.

Inclusion criteria (patients)

Female or male adult patients (18-65), able to understand Chinese or English, with a ICD-10 diagnosis of SMI (classified as schizophrenia, schizoaffective disorder, other psychotic disorder, bipolar affective disorder [type 1 or 2] or major depressive disorder).

Sample size:

This is a pilot study and the main objective is to provide information about required sample sizes for the main trial; therefore, we were unable to take reference from any previous CHIP study and our sample size calculation was based on a standard deviation of around 12 points for the SF36v2/SF12v2 PCS observed in SMI patients and an estimated mean difference of 6 points on this scale between intervention and TAU groups (suggestive of a medium-to-large effect size) (White et al., 2011; Lam et al., 2013). As the 12 CPNs involved in the study were the clustered units of randomisation we also needed to adjust the sample size calculation accordingly. Assuming an intraclass correlation of 0.15 (White et al., 2011) and a significance level of 0.05, we calculated that for a medium (0.5) effect size the number of patients required would be 21 per nurse and for a large (0.8) effect size we would need 3 patients per nurse. Given that our previous case series study (Bressington et al., 2014) demonstrated patient attrition was approximately 29%, we inflated our sample size accordingly. Therefore, as this pilot study aimed to detect a medium-large effect size, the 12 CPNs were asked to recruit and (where appropriate) deliver the intervention to 12 patients each that were randomly selected from their caseloads (effectively 72 in each group).

Intervention:

CPNs allocated to the intervention group used the CHIP to assess patients' physical health risk and identify problem health and lifestyle behaviours. The CHIP tool consists of 27 areas of physical health assessment for men and 28 areas for women (including BMI, waist circumference, blood pressure, pulse, cholesterol levels, dietary habits, exercise levels, fluid intake, alcohol use, substance misuse, self-checking behaviours, smoking status, regularity of health check-ups, bowel habits, sleep, urination concerns, caffeine intake, sexual functioning and safe-sex practices), it also provides information about healthy parameters and suggestions for evidenced-based interventions to address areas of identified health risks. In line with the procedures described by White, Gray and Jones (2009) and Shuel et al (2010), findings from the assessment were used to inform an individualised care plan with community based patients with SMI. CPNs were encouraged to use this plan to liaise with medical colleagues to refer patients for further investigation or treatment as required. The CHIP used a traffic light system to indicate area of physical health risk that require attention (green= no action required; yellow= caution; red=action required). The yellow (caution) flag was used for the majority of items except those with well-defined cut-off parameters (BMI, waist circumference, pulse, blood pressure, liver function, prostate/testicles check, cervical smear test, feet check, breast check, menstrual cycle and smoking status). The CPNs then used brief motivational interviewing techniques and principles to have conversations about and support health behaviour change (as outlined by Hardy, White and Gray, 2015; White et al., 2011; Meerpring et al., 2016) during monthly follow-up meetings. Each completion of the CHIP tool takes around 25 minutes and CPNs were expected to discuss/review the care plans for a minimum of 15 minutes each month. The overall emphasis of the intervention was to raise patients' awareness of their own physical health and encourage self-management/behaviour change.

CHIP training:

The CPNs in the intervention group attended a one-day training workshop (facilitated by DB, KL and JM). The learning outcomes from the workshop were: 1. using the CHIP, 2. behaviour change conversations using brief motivational interviewing techniques, and 3. care planning and follow-up. Participants who attended reported that they felt confident that they had an adequate level of skills and a good understanding of the CHIP intervention prior to using the intervention with their patients. They were all provided with clinical supervision in monthly meetings with their team supervisors as well as 6-monthly multidisciplinary case meetings chaired by the consultant psychiatrist; other than these usual regular meetings no extra support was required.

Treatment as usual:

Patients in both the intervention and control groups received routine community mental health services and attended psychiatric outpatient appointments as required. Both patient groups also received annual basic physical health screening (as specified by the policy of the clinical setting for people taking antipsychotics) to measure waist circumference, BMI, blood glucose, cholesterol levels and blood pressure.

Outcome measures:

Patients' outcomes (SF12v2) were measured at baseline and 6 and 12 months after starting the intervention. Relevant demographic/clinical patient data were recorded at baseline and at 12 months. Data relating to the participants' physical health state that had been routinely recorded over the one-year duration of the study were extracted from their integrated medical records. These data included indicators of cardiometabolic health recorded by nursing staff (i.e. body temperature, waist circumference, weight, BMI, heart rate, blood pressure,) and relevant blood test results (i.e. cholesterol, liver function, prolactin levels, fasting blood glucose levels).

Intervention and TAU groups:

Patients physical well-being was measured using the physical component subscale (PCS) of the SF12v2. Perceived mental health was determined using the mental component subscale (MCS) of SF12v2. The SF12v2 (Ware et al. 2000) is modified from the original SF36 and includes 12 questions (Ware et al., 1994). The Hong Kong version of the SF12v2 is reporting as having acceptable test–retest reliability (intraclass correlation 0.82) and also has acceptable internal consistency (Cronbach's alpha 0.67). Sensitivity and construct validity were also confirmed in a Chinese population (Lam et al., 2013).

Data relating to patients' physical state that are routinely recorded in medical/outpatient/nursing notes during the study were also compared between the two groups.

Intervention group only:

Data recorded from the individual items of the CHIP (red flagged physical health risks and health behaviours) were compared between baseline and at 12 months after the start of the intervention. We also identified the numbers of individual participants that improved or deteriorated in terms of their CHIP item classification over the duration of the study.

Ascertaining the acceptability of CHIP intervention programme:

In order to measure patients' views about their satisfaction with their physical health care (treatment as usual and CHIP intervention programme group) we asked all patients to complete the Chinese language version of the Client Satisfaction Questionnaire (CSQ8) (Attkisson and Zwick, 1982; Attkisson, 2012) 12 months after the intervention. The CSQ8 is a well-established standardised self-report measure of client/patient satisfaction with a service or intervention. It consists of 8 Likert scale questions and has been used in many patient groups and service settings; including physical and mental health conditions. It is reported to have excellent reliability and internal consistency (Attkisson and Zwick, 1982). In order to ascertain CPNs perspectives about the perceived acceptability and usefulness of the CHIP intervention at 12 months' follow-up we asked all participants in the intervention group to complete a simple questionnaire

containing two 8-point Likert scale questions of "usefulness" and "acceptability" of the CHIP on scale from 1 (not at all) to 9 (very useful) and an optional box for additional feedback.

Intervention fidelity:

CPNs fidelity to the CHIP intervention was established through a clinical notes audit of a randomly selected group of participants. All participants from the intervention group were assigned a new number and 20% (N=14) of the CHIP patients were randomly chosen using a list of computer-generated numbers (using researchrandomiser.org). At 12 months, 2 researchers examined the medical and nursing notes of these randomly selected patients. The notes were checked to establish how many recommendations/interventions identified using the CHIP were also mentioned in the participants' care plans.

Data analysis

Intervention and TAU groups

Baseline characteristics were summarized and compared between the study groups (table 1). The primary analysis included comparing the primary outcome of PCS-12 at 12 months between the study groups using the one-way analysis of variance (ANOVA) with adjustment for the possible clustering effect among the nurses (table 2). The Intra-class correlation coefficient was computed. The secondary analyses included performing similar analysis for the PCS-12 score at 6 months and for the MCS-12 scores at 6 and 12 months and several secondary variables such as BMI, waist circumference, blood pressure, pulse and total cholesterol. Moreover, the analyses were adjusted for the baseline values in PCS-12 and MCS-12 using one-way analysis of covariance (ANCOVA) that also adjusts for the clustering effect. Independent t-tests were utilised to measure differences between the two groups on CSQ8 scores at 12 months' follow-up. The intention to treat (ITT) was used throughout all analyses with missing data from randomised patients imputed using the overall mean values at each time point.

Intervention group only:

McNemar tests, Wilcoxon signed rank test, paired T-tests or Freidman's' two-way ANOVA (dependent on the variable type and distribution of data) were used to analyse differences between baseline and follow-up data on frequency of red/green/yellow flagged health behaviours and physical health parameters recorded on the CHIP tool within the intervention group. These analyses provided an indication of within-group changes in self-reported health behaviours and physical indicators of physical health risk that are recorded as part of the CHIP intervention.

Results

Figure 1 shows the flow of CPNs and patients through the trial. A total of 165 eligible outpatients (15 per CPN) were randomly selected and approached to take part, of these, 141 (85%) consented to take part and

were assessed at baseline. The remaining 23 (15%) expressed no interest in completing the CHIP, and one received a diagnostic change during the recruitment period necessitating exclusion from the study. Of the 141 patients who provided initial consent, 4 were withdrawn from the study prior to randomisation (two were moved under the care of a different CPN and two were discharged from CPS). Recruitment of participants to the study was completed in September 2015.

12 CPNs were randomized into either the Treatment as Usual (TAU) group or the Chinese Health Improvement Profile (CHIP) intervention group by September, 2015, resulting in 69 patients randomized into the CHIP group and 68 patients into the TAU group. Both groups completed their 6-month follow-up outcome measures by March 2016, with one CHIP patient lost to follow-up (discharged from the service). The 12 months' follow-up measures were completed between June and September 2016, with 10 patients from CHIP and 4 patients from TAU were further lost to follow-up. Reasons for attrition were: 3 patients required case managerial changes due to operational reasons, one patient moved out of area, 2 cases due to hospital readmission, 5 participants refused to complete outcome measures and 4 patients were discharged from the service (completed treatment). In accordance with the a-priori intention-to-treat analysis strategy 69 patients in the CHIP group and 68 TAU patients were included in the final analysis. No significant physical health related adverse effects were reported as a result of the intervention throughout the study, however two patients in the CHIP group were admitted to hospital for relapse of mental illness.

Baseline demographic and clinical characteristics

The baseline demographic and clinical characteristics of participants are provided in table 1. Overall, the patients in both groups were predominantly middle-aged with a mean of 47.8 years (SD= 9.2) in the CHIP group and mean of 46.8 years (SD=10.4) in the TAU group. On average the patients had a duration of illness of around 14 years. Over half (55%) were diagnosed with schizophrenia and two thirds (64%) were being treated with atypical antipsychotic medications. Most of the baseline characteristics were not different between the two study groups except for Dyslipidaemia (p=0.06), Pulse (p=0.001) and Systolic Blood Pressure (p=0.03).

Primary and secondary outcomes

Table 2 shows the analysis results for the primary and table 3 shows the secondary outcome measures.

There was a positive trend of changes in the mean PCS-12 scores of the CHIP group throughout the study, with a 2.6 mean increase from baseline to 6 months, and a further increase of 1.1 from 6 to 12 months. As opposed to the TAU group in which the PCS-12 scores initially increased from baseline to 6 months (mean difference of 2.2), before deteriorating by 0.6 to a mean score of 47.5 at 12 months. However, at 12 months there was no statistically significant difference found in the mean PCS-12 scores between the two study groups (50.7 in the CHIP vs. 47.5 in the TAU group, p=0.149). The ICC was 0.158 for the cluster effect. The

results did not change greatly when the analysis was adjusted for baseline values (mean difference of 2.7, p=0.138). The preliminary effect size of the differences between CHIP and TAU groups in mean PCS-12 scores at one-year is calculated as Cohen's *d*=0.42.

Positive trends were also observed for the MCS-12 scores, with steady improvements for the CHIP group throughout the study (increase in mean MCS-12 score of 5) compared to the TAU group (overall increase of 0.8). However, similarly to the primary outcomes, the differences for the MCS12 score (adjusted for baseline scores) between the two groups at 12 months did not reach statistical significance (p=0.077). Table 3 shows the data analysis for the secondary outcomes. Except for pulse where participants in the CHIP group had significantly lower mean than those in the TAU group (p=0.006), none of the other secondary variables considered were significantly different between the study groups at 12 months.

Within-group CHIP item changes

Table 4 provides details of the CHIP items at baseline and 12-months. The results show there are significant (within CHIP group) improvements in the frequencies of red/yellow/green flagged individual items for Prostate/testicles checks (p=0.025), Feet checks (p<0.001), Breast checks (p=0.002), Diet (fruit and vegetables; p=0.008), Diet (rice; p=0.041), Fluid intake (p=0.001), Total Red flags (Z=-2.81, p=.005) and Total Green flags (Z=-3.13, p=.002). The percentage of women with concerns about their menstrual cycle was the only item observed to have significantly deteriorated (p=0.021). The numbers of individual participants that improved or deteriorated in terms of their classification are also detailed in table 4.

Patient satisfaction

Analysis of the CSQ8 scores at 12 months' revealed that participants in the CHIP group (mean 26.68) were significantly more satisfied with their physical health care provision than those patients in the TAU group (mean 25.41) with a mean difference of 1.27 (p=0.009, T -2.67, df135, 95% CI -2.21 to -0.33).

Nurse perceived usefulness and acceptability

The six CHIP CPNs scored the mean perceived usefulness of the intervention as 7.5/9 (range 7-9, median=7) and acceptability as 7.1/9 (range 6-9, median=7). The majority (5) commented that the use of the CHIP intervention helped to effectively raise patient's awareness (or insight) of their physical health status and was a useful approach to help the CPNs motivate patients to make positive lifestyle behaviour changes. Identified areas for improvement were mentioned by two nurses; the first suggested to abandon using the carbon backed paper used to copy writing onto the patient copy of the CHIP tool (as this was felt to be too messy/unclear) and the second felt that it would be more acceptable if the amount of writing required of the CPN could be reduced.

Intervention fidelity

The review of randomly selected patients notes showed that whilst every CPN highlighted more than one recommendation and written advice for further investigation on the CHIP form, only 50% (N=7) of the 14 patient care plans examined included such advice. However, noting that the design of the CHIP form expected CPNs to provide a copy of the completed tool directly to the patient, the lack of inclusion of all information/advice in the care plans may have been expected, particularly in view of the necessarily brief nature of their case notes.

Discussion

There was an observed positive trend of improvement on PCS-12 and MCS-12 scores in the CHIP group compared to the TAU group after 12 months. However, these improvements did not reach statistical significance, primarily because the sample size was inadequate for the present pilot study to detect significant differences as it was calculated assuming a medium to large effect size.

The significant within-group improvements in frequencies of red/yellow/green CHIP flagged items suggest that the intervention has raised the participants' awareness of the need to focus on their physical health and associated health-behaviours. However, on this occasion these modest positive changes have not resulted in statistically significant improvements in the primary or secondary study outcomes. It is possible that these small improvements could continue after the 12-month period and it would be beneficial for future studies to conduct a longer term follow-up to measure effects post-one year. The lack of improvements in the main study outcome measure may relate to the relatively high baseline scores of participants (measured using the SF12v2), hence creating a ceiling limit for potential improvements. For example, published norm-based scores (Lam et al., 2013) suggest that within a Chinese population of people with diagnosis of a psychological illness the mean score of the SF12v2 PCS is 44.13, whereas the baseline scores in the current study for the CHIP and TAU groups were 47.0 and 45.9 respectively. Despite this ceiling limit, the one-year PCS-12 scores in the CHIP group (50.7) increased to levels in excess of norm-based scores for the Hong Kong population aged 41-64 years (49.23) (Lam et al., 2013). In addition, as the CHIP was only used at baseline and at 12-month follow-up (in accordance with the original HIP procedures (White et al., 2009; Shuel et al., 2010; White et al., 2011), it is possible that this may not be an adequate "dose" of the intervention, therefore we would suggest increasing the frequency of completion to 3 or 6 monthly over a duration of one year. Another potential reason for the lack of significant differences between the two groups may arguably be because the increased attention of mental health nurses towards the physical health of service users and sharing of information has created a generally more positive environment for monitoring and managing physical health (i.e. that the service has improved for all participants). However, the higher satisfaction scores seen in the CHIP group do seem to indicate that even if the service had improved generally, the CHIP participants were still more satisfied than those in the TAU group.

The participants in this study reported relatively low levels of substance use. Compared to HIP participants in Scotland (Shuel et al., 2010) service users in the current study had lower frequencies of red-flagged items for caffeine intake (0% vs 6.5%), alcohol (3% vs 19%) and drug use (1% vs 7%). However, there was higher percentage of smokers in Hong Kong (35%) than in Scotland (26%). Whilst HIP findings from an inpatient HIP study in the UK (White, 2015) show that rates of red-flagged items were higher than Hong Kong for alcohol use (45%), caffeine intake (33%, smoking (54%) and drug use (25%). It is possible that participants in the current study may have underreported their use of substances, but the frequency of red-flagged items for substance use in the current study are broadly similar to our earlier case series study (Bressington et al., 2014) which was carried out in the same clinical setting (alcohol 6%, smoking 27%, caffeine 5%). There are very few other studies which have reported the health behaviours of people with SMI in South East Asia, however; one HIP study conducted in Thailand (Thongsai et al., 2016) reports lower percentages of red-flags than Hong Kong in most substance use areas (alcohol 2%, smoking 12%, illegal drugs 7%). This body of evidence seems to show that mental health nurses in some South-East Asian countries may face less substance use related health promotion challenges than their counterparts in Western countries. Despite this, one of the main challenges for mental health nurses in Hong Kong relates to the high numbers of patients who are obese (55%).

Much effort has been put into testing interventions to reduce the bodyweight of SMI patients with pre-existing cardiometabolic health risks, unfortunately the vast majority of evidence suggests that completely reversing these risks is extremely difficult (Attux et al., 2011; Mitchell and DeHert, 2015). The mean age of participants in the current study was 47 years and average duration of illness was 14 years, it is certainly possible that marked changes are less likely for older patients and those with long history of SMI (Mitchell and DeHert, 2015; Bonfioli et al., 2012), and therefore this may account for the lack of improvement in objective indicators of obesity. It is now becoming quite clear that the management of obesity in patients with SMI requires early recognition, frequent monitoring, multidisciplinary treatment and approaches to build the motivation of patients to address potential/actual health risks (Manu et al., 2015; Mitchell and DeHert, 2015). The CHIP intervention contains these important elements, but in this instance it has not been used to facilitate early recognition of cardiometabolic health risks. If the CHIP intervention is started at the first point of contact with people with a SMI this may serve to off-set the build-up of cardiometabolic risk factors rather than intervening once a related physical illness has been identified (Mitchell and DeHert, 2015). Our recently published HIP-T quasi experimental study involving 105 people with schizophrenia in Thailand (Meepring et al., 2016) showed a statistically significant reduction of average BMI (3.5% change, $p<0.001$), while a post-hoc subgroup analysis of patients (n=25) with early psychosis (i.e., not more than one-year onset of the illness) found a potentially clinically significant improvement[41] of >5% reduction of BMI ($p=0.01$, Cohen's $d=0.32$). Suggesting that the CHIP intervention is likely to be more effective in patients with early stage of psychosis recently prescribed antipsychotics than in those patients with a longer duration of SMI. People with early stage psychosis may be more receptive towards interventions designed to raise awareness of the importance of preventing physical health problems and to enhance motivation/self-

efficacy for managing health than those people who have a longer duration of illness (Carney, Bradshaw and Yung, 2016). Service users who have experienced psychosis for long periods may subsequently develop cognitive impairments, marked negative symptoms and metabolic side effects from antipsychotics. All of these illness/treatment-related consequences can present significant barriers towards building an individual's capability, opportunities, and motivation to make healthy lifestyle changes (Michie et al., 2015; Armitage and Conner, 2001).

In terms of acceptability the intervention and feasibility of conducting a full-scale study; the CHIP participants were significantly more satisfied with their physical healthcare than TAU patients at one-year, suggesting that the CHIP intervention is viewed as being helpful by patients. Similarly, the CHIP CPNs viewed the approach as being generally useful and acceptable from their perspectives. The audit of randomly selected clinical notes suggests that CPNs fidelity to the intervention was maintained in at least half of cases. The attrition rate was also relatively low for this patient group (11%, 15 participants), suggesting that patients viewed participation in the trial as being acceptable.

Study limitations

The study limitations should be considered when interpreting the results. The lack of blinding of outcome measurement may have produced an expectation or response bias, the health behaviours were self-reported by participants and not objectively verified, and the sample size for this pilot trial has resulted in an inadequate powered study to detect a small effect size for the primary outcome measure after adjusting for the clustering effect and baseline scores. However, the process of randomly selecting patient participants and randomisation of patients into treatment arms adds to the study's internal validity.

Conclusions:

The results of this study indicate that it is feasible to conduct a full-scale RCT of the CHIP in future. Both patients and CPNs generally viewed the approach as being acceptable and useful. The CHIP is a low risk and easily accessible intervention that could result in modest improvements in the physical well-being of people with SMI. Future studies of the CHIP using the PCS of the SF12v2 as a primary outcome measure should consider using an effect size of 0.42 for sample size calculations.

Relevance for clinical practice:

The study findings provide further evidence that people with SMI will engage effectively in health-check interventions designed to improve their physical well-being when these are conducted by their CPNs. Physical health checks and associated brief motivational interviewing interventions should be conducted frequently and as early as possible in treatment to maximise the potential benefits.

References:

American Psychiatric Association. Practice Guideline for the Treatment of Patients With Schizophrenia. 2004; DOI: 10.1176/appi.books.9780890423363.45859

Armitage, C. J., & Conner, M. (2001). Efficacy of the theory of planned behaviour: A meta-analytic review. *British journal of social psychology*, 40(4), 471-499.

Attkisson, C.C., & Zwick, R. (1982). The Client Satisfaction Questionnaire: Psychometric properties and correlations with service utilization and psychotherapy outcome. *Evaluation and Program Planning*, (593), 233-237.

Attkisson, C.C. (2012). The CSQ Scales Reprint Portfolio. Mill Valley, CA: Tamalpais Matrix Systems, LLC.

Attux, C., Martini, L.C., Araújo, C.M., et al. (2011). The effectiveness of a non-pharmacological intervention for weight gain management in severe mental disorders: results from a national multicentric study. *Revista Brasileira de Psiquiatria*, 33:117–121.

Bartels, J., Pratt, S.I., Aschbrenner, K.A., et al. (2013). "Clinically significant improved fitness and weight loss among overweight persons with serious mental illness." *Psychiatric Services*, 64.8: 729-736.

Bonfioli, E., Berti, L., Goss, C., et al. (2012). Health promotion lifestyle interventions for weight management in psychosis: a systematic review and meta-analysis of randomised controlled trials. *BMC Psychiatry*, 12(1):78.

Bressington, D., Mui, J., Hulbert, S., Cheung, E., Bradford, S. and Gray, R. (2014). Enhanced physical health screening for people with severe mental illness in Hong Kong: results from a one-year prospective case series study. *BMC Psychiatry*, 14 (57).

Bressington, D., Mui, J., Wells, H., et al. (2016). Refocusing on Physical Health: Community Psychiatric Nurses' Perceptions of Using Enhanced Health Checks for People with Severe Mental Illness. *International Journal of Mentel Health Nursing*,25:214–224. doi: 10.1111/inm.12195

Brown, S., Inskip, H., Barraclough, B. (2000). Causes of the excess mortality of schizophrenia. *The British Journal of Psychiatry*, 177:212-217.

Buka, S. L. (2008). Psychiatric epidemiology: Reducing the global burden of mental illness. *American Journal of Epidemiology*, 168, 977.

Carney, R., Bradshaw, T., & Yung, A. R. (2016). Physical health promotion for young people at ultra-high risk for psychosis: An application of the COM-B model and behaviour-change wheel. *International Journal of Mental Health Nursing*, 25(6), 536-545.

Chesney, E., Goodwin, G.M., & Fazel, S. (2014) Risks of all-cause and suicide mortality in mental disorders: A meta-review. *World Psychiatry*, 13:153–160.

DeHert, M., Correll, C., Bobes, J., et al. (2011) Physical illness in patients with severe mental disorders. Prevalence, impact of medications and disparities in health care. *World Psychiatry*; 10:52-77

Department of Health (2006). *Improving the physical health of people with mental health problems: Actions for mental health nurses*. Nursing, Midwifery and Allied Health Professions Policy Unit, NHS England. London.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/532253/JRA_Physical_Health_revised.pdf

Eldridge, D., Dawber, N., Gray, R. (2011). A well-being support program for patients with severe mental illness: a service evaluation*. BMC Psychiatry*. 11:46 doi:10.1186/1471-244X-11-46

Ellis, N., Crone, D., Davey, R. & Grogan, S. (2007). Exercise interventions as an adjunct therapy for psychosis: A critical review. *British Journal of Clinical Psychology*, 46, 95–111.

Firth, J., Cotter, J., Elliott, R., et al. (2015). A systematic review and meta-analysis of exercise interventions in schizophrenia patients. *Psychological. Medicine,* 45:1343–1361.

Gardner-Sood, P., Lally, J., Smith, S., et al. (2014). Cardiovascular risk factors and metabolic syndrome in people with established psychotic illnesses: Baseline data from the IMPaCT randomized controlled trial. *Psychological Medicine*, 45:2619–2629.

Happell, B., Davies, C., & Scott, D. (2012). Health behaviour interventions to improve physical health in individuals diagnosed with a mental illness: A systematic review. *International Journal of Mental Health Nursing*, 21(3), 236-247.

Hardy, S. White, J., & Gray, R. (2015) *The Health Improvement Profile: A manual to promote physical wellbeing in people with severe mental illness.* Keswick, M & K Publishing. ISBN: 9781905539918.

Lam, E. T., Lam, C. L., Fong, D. Y., & Huang, W. W. (2013). Is the SF-12 version 2 Health Survey a valid and equivalent substitute for the SF-36 version 2 Health Survey for the Chinese?. *Journal of Evaluation in Clinical Practice*, 19(1), 200-208.

Lawrence, D., Hancock, K.J., & Kisely, S. (2013). The gap in life expectancy from preventable physical illness in psychiatric patients in Western Australia: retrospective analysis of population based registers. *British Medical Journal*, 346:f2539.

Levi, J., Segal, L., St. Laurent, R., et al. (2012). F as in Fat: *How Obesity Threatens America's Future 2012*. Trust for America's Health/Robert Wood Johnson Foundation. http://www.rwjf.org/content/dam/farm/reports/reports/2012/rwjf401318

Manu, P., Dima, L., Shulman, M., Vancampfort, D., et al. (2015). "Weight gain and obesity in schizophrenia: epidemiology, pathobiology, and management." *Acta Psychiatrica Scandinavica*, 13(2):97-108.

McEvoy, J.P., Meyer, J.M., Goff, D.C., et al. (2005). Prevalence of the metabolic syndrome in patients with schizophrenia: Baseline results from the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) schizophrenia trial and comparison with national estimates from NHANES III. *Schizophrenia Research,* 80(1):19-32.

Meepring, S., Chien, WT., Gray, R., Bressington, D. (E-pub ahead of Print 2016). The effects of the Thai Health Improvement Profile intervention (HIP-T) on the physical health and health behaviours of people with schizophrenia: A quasi experimental study. *International Journal of Mental Health Nursing,* 2016. doi: 10.1111/inm.12301

Michie, S., Wood, C. E., Johnston, M., Abraham, C., Francis, J. & Hardeman, W. (2015). Behaviour change techniques: the development and evaluation of a taxonomic method for reporting and describing behaviour change interventions (a suite of five studies involving consensus methods, randomised controlled trials and analysis of qualitative data). *Health Technology Assessment*, 19(99).

Mitchell, A.J., De Hert, M. (2015). Promotion of physical health in persons with schizophrenia: can we prevent cardiometabolic problems before they begin? *Acta Psychiatrica Scandinavica*, 132(2):83-85

NICE. (2014). Psychosis and Schizophrenia in Adults (National Clinical Guideline Number 178). London: *National Collaborating Centre for Mental Health*.

Ohlsen, R.I., Peacock, G., & Smith, S. (2005). Developing a service to monitor and improve physical health in people with serious mental illness. *Journal of Psychiatric and Mental Health Nursing*, 12:614–619

Robson, D., Gray, R. (2007). Serious mental illness and physical health problems: a discussion paper. *International Journal of Nursing Studies*, 44:457−466.

Rosenbaum, S., Tiedemann, A., Sherrington, C., et al. (2014). Physical activity interventions for people with mental illness: a systematic review and meta-analysis. *Journal of Clinical Psychiatry,* 75:964–974.

Saxena, S., Van Ommeren, M., Tang, K. C., & Armstrong, T. P. (2005). Mental health benefits of physical activity. *Journal of Mental Health*, 14(5), 445-451.

Soundy, A., Freeman, P., Stubbs, B., et al. (2014). The transcending benefits of physical activity for individuals with schizophrenia: a systematic review and meta-ethnography. *Psychiatry* Research, 220:11–19.

Shuel, F., White, J., Jones, M., Gray, R. (2010). Using the serious mental illness health improvement profile [HIP] to identify physical problems in a cohort of community patients: a pragmatic case series evaluation. *International Journal of Nursing Studies*, 47:136-145

Vancampfort, D., Stubbs, B., Mitchell, A.J., et al. (2015). Risk of metabolic syndrome and its components in people with schizophrenia and related psychotic disorders, bipolar disorder and major depressive disorder: A systematic review and meta-analysis. *World Psychiatry*, 14:339–347.

Van Meijel, B., Van Hamersveld, S., Van Gool, R., Van Der Bijl, J., Van Harten, P. (2014). Effects and Feasibility of the "Traffic Light Method for Somatic Screening and Lifestyle" in Patients With Severe Mental Illness: A Pilot Study. *Perspectives in Psychiatric Care*.

Veerland, S., Minsky, M., Menza, R.D., Rigassio, B., Roemhold-Hamm, R., Stern (2003). A programme for managing weight gain associated with atypical antipsychotics. *Psychiatric Services*, 54, 1155–1157.

Walker E.R., McGee R.E., Druss, B.G. (2015) Mortality in mental disorders and global disease burden implications: A systematic review and meta-analysis. *JAMA Psychiatry,* 72:334–341

Ware, J.E. Jr, Kosinski, M., Dewey, J.E. (2000) *How to Score Version 2 of the SF-36® Health Survey (Standard & Acute Forms)*. Lincoln, RI: QualityMetric Incorporated.

Ware, J.E., Kosinski, M., Keller, S. (1994). *SF-36 physical and mental health summary scales: a user's manual*. Health Assessment Lab.

White, J. (2015). *Physical health checks in serious mental illness: a programme of research in secondary care* (Doctoral dissertation, University of East Anglia). https://ueaeprints.uea.ac.uk/56777/1/J_White_HSC_4393376_PhD_Thesis_FINAL_submitted_22-05-2015.pdf

White, J., Gray, R., Jones, M. (2009). The development of the serious mental illness physical Health Improvement Profile. *Journal of Psychiatric and Mental Health Nursing*, 16:493-498.

White, J., Gray, W., Swift, L., et al. (2011). The serious mental illness health improvement profile [HIP]: study protocol for a cluster randomised controlled trial. *Trials* 2011;12(1):167. doi: 10.1186/1745-6215-12-167

Wirshing, D,. Smith, A., Erickson, Z., Mena, S., Wirshing, W. (2006). A wellness class for inpatients with psychotic disorders. *Journal of Psychiatric Practice*, 12(1), 24–29

Table 1: Baseline socio-demographic and clinical characteristics of the CHIP and TAU groups

Characteristics	CHIP (n= 69)	TAU (n= 68)	Test value	df	P
Gender (f, %)			2.10[a]	1	0.17
Male	29, 42.0	37, 54.4			
Female	40, 58.0	31, 45.6			
Age (years, mean±SD)	47.8±9.2	46.8± 10.4	0.59[b]	135	0.56
Education level (f, %)			1.12[a]	2	0.57
Primary school or below	25, 36.2	19, 27.9			
Secondary school	37, 53.6	42, 61.8			
College or University	7, 10.1	7, 10.3			
Marital status (f, %)			0.67 [a]	4	0.96
Single	23, 33.3	19, 27.9			
Married	24, 34.8	27, 39.7			
Divorced	13, 18.8	12, 17.6			
Widowed	3, 4.3	3, 4.4			
Other	6, 8.7	7, 10.3			
Living situation (f, %)			3.19 [a]	3	0.36
With family	43, 62.3	44, 64.7			
Alone	16, 23.2	17, 25.0			
Hostel	9, 13.0	5, 7.4			
Other	0, 0.0	2, 2.9			
Financial support (f, %)			0.86 [a]	2	0.65
Government benefits	58, 84.1	55, 80.1			
Family	5, 7.2	8, 11.8			
None	6, 8.7	5, 7.4			

Primary psychiatric diagnosis (f, %)			2.36 [a]	3	0.50
Schizophrenia	39, 56.5	37, 54.4			
Major depression	16, 23.2	17, 25.0			
Bipolar affective disorder	9, 13.0	5, 7.4			
Other psychotic disorders	5, 7.2	9, 13.2			
Duration of psychiatric illness (months, mean±SD)	170.4±136.6	160.9±126.9	0.42 [b]	133	0.68
Number of previous psychiatric admissions (mean±SD)	3.44±4.6	2.54±2.81	1.35 [b]	129	0.18
Physical illness diagnosis (f, %)					
Diabetes	10, 14.5	7, 10.3	0.61 [a]	1	0.44
Hypertension	9, 13.0	4, 5.8	2.13 [a]	1	0.15
Dyslipidaemia	5, 7.2	0, 0.0	5.20 [a]	1	**0.06***
Physical state indicators (mean±SD)					
BMI (kg/m2)	24.05±3.8	25.13±3.5	1.72 [b]	134	0.09
Waist circumference (cm)	85.8±12.5	85.2±10.1	0.29 [b]	134	0.76
Pulse (bpm)	78.0±9.6	85.8±11.4	4.33 [b]	134	**0.001***
Systolic BP (mm/hg)	120.9±14.2	125.9±12.5	2.21 [b]	135	**0.03***
Diastolic BP (mm/hg)	76.8±9.3	78.4±8.7	1.06 [b]	135	0.29
Total Cholesterol	4.9±1.1	4.9±0.9	0.02 [b]	111	0.99
LDL cholesterol	2.8±0.8	2.9±0.8	0.62 [b]	101	0.53
HDL cholesterol	1.3±0.4	1.2±0.4	1.16 [b]	104	0.25
Serum glucose	5.5±1.5	5.5±1.6	0.05 [b]	130	0.96
Type of antipsychotic medication (f,%)					
Conventional antipsychotics	20, 28.9	22, 32.4	1.44 [a]	1	0.21
Atypical antipsychotics	44, 63.8	44, 64.7	0.01 [a]	1	0.91
Long acting Antipsychotic injections	18, 26.1	17, 25.0	0.02 [a]	1	0.88
Number of different antipsychotics	1.1, 0.6	1.1, 0.7	0.26 [a]	135	0.80

(mean±SD)

Note: CHIP, Chinese Health Improvement Profile ; TAU, Treatment-As-Usual.

[a] Tested by $\chi 2$

[b] Tested by Independent Samples T-test.

Table 2: Data analysis of the primary outcome

Variable	CHIP mean±SE	TAU mean±SE	ICC	Difference (adjusted for clustering) mean±SE	P-value (Adjusted for clustering)
PCS-12 (Baseline)	47.0±0.8	45.9±0.8	0.061	1.1±1.5	0.474
PCS-12 (6months)	49.6±1.0	48.1±1.0	0.009	1.5±1.4	0.310
PCS-12 (6months) Adjusted for baseline				1.1±1.3	0.400
PCS-12 (12 months)	50.7±0.7	47.5±1.1	0.158	3.2±2.1	0.149
PCS-12 (12 months) adjusted for baseline				2.7±1.7	0.138

Table 3: Data analysis for the secondary outcomes

Variable	CHIP mean±SE	TAU mean±SE	ICC	Difference (adjusted for clustering) mean±SE	P-value (Adjusted for clustering)
MCS-12 (Baseline)	43.8±1.5	45.2±1.3	0.058	-1.4±2.3	0.551
MCS-12 (6months)	47.0±1.2	45.3±0.9	0.162	1.78±2.4	0.474
MCS-12 (6months) adjusted for baseline scores				1.93±2.3	0.416
MCS-12 (12 months)	48.8±1.1	46.0±0.9	0.059	2.8±1.8	0.147
MCS-12 (12 months) adjusted for baseline scores				3.2±1.6	0.077
BMI follow-up	24.3±0.5	25.1±0.5	0.130	-0.7±1.0	0.464
Waist circumference follow-up	85.5±1.6	84.9±1.2	0.218	0.6±3.4	0.856
Pulse follow-up	77.6±1.2	85.4±1.1	0.124	-7.8±2.3	0.006*
Systolic BP follow-up	118.7±2.1	123.6±1.5	0.224	-4.9±4.3	0.278
Diastolic BP follow-up	75.6±1.4	77.1±1.0	0.147	-1.5±2.5	0.554
Total Cholesterol Follow-up	4.3±0.2	4.6±0.2	0.397	-0.3±0.5	0.569

*significant difference ($p \leq 0.05$)

Table 4: CHIP flagged items at baseline and one-year follow-up

CHIP items (Patient classification changes baseline to follow-up)	Baseline (n=69) N (valid %)^	Follow-up (n=59) N (valid %)^	p value (Test result)
BMI			
Red	42 (60.9)	35 (60.3)	p= 1.000[†]
Green	27 (39.1)	23 (39.7)	
(Improved=6, Deteriorated=6)			
Waist circumference			
Red	38 (55.1)	31 (54.4)	p=1.000[†]
Green	30 (44.1)	26 (45.6)	
(Improved=5, Deteriorated=5)			
Blood pressure			
Red	6 (8.7)	3 (5.2)	p=1.000[†]
Green	63 (91.3)	55 (94.8)	
(Improved=3, Deteriorated=2)			
Pulse			
Red	1(1.4)	1 (1.7)	p=1.000[†]
Green	68 (98.6)	57 (98.3)	
(Improved=0, Deteriorated=0)			
Liver Function Test			p=.564 [a]
Red	42 (60.9)	35 (60.3)	
Yellow	12 (17.4)	10 (17.2)	
Green	15 (21.7)	13 (22.4)	
(Improved=13, Deteriorated=14)			
Total Cholesterol			p=.366 [a]
Red	6 (8.8)	4 (6.9)	
Yellow	27 (39.7)	24 (41.4)	
Green	35 (51.5)	30 (51.7)	
(Improved=5, Deteriorated=6)			
LDL Cholesterol			p=1.000
Red	5 (7.2)	8 (13.8)	
Yellow	16 (23.2)	10 (17.2)	
Green	48 (69.6)	40 (69.0)	
(Improved=3, Deteriorated=7)			
HDL Cholesterol			p=.617 [a]
Red	26 (38.2)	20 (34.5)	
Yellow	15 (22.1)	10 (17.2)	
Green	27 (39.7)	28 (48.3)	
(Improved=8, Deteriorated=7)			
Triglycerides			p=.593 [a]
Red	13 (21.0)	14 (24.1)	
Yellow	19 (30.6)	10 (17.2)	
Green	30 (48.4)	34 (58.6)	
(Improved=8, Deteriorated=6)			
Serum glucose			p=.059[†]
Red	5 (7.5)	5 (8.6)	

Yellow	3 (4.3)	4 (6.9)	
Green	59 (88.1)	48 (82.8)	
(Improved=1, Deteriorated=6)			
Prostate/testicles (male, baseline n= 29)			
Red	28 (93.3)	17 (77.3)	***p*=.025**[a]
Yellow	0 (0.0)	0 (0.0)	
Green	1 (3.3)	5 (22.7)	
(Improved=5, Deteriorated=0)			
Cervical smear (female, baseline n=40)			*p*=.375[†]
Red	24 (60.0)	17 (47.2)	
Green	16 (40.0)	19 (52.8)	
(Improved= 5, Deteriorated=1)			
Sleep			
Red	1 (1.4)	1 (1.7)	*p*=..564 [a]
Yellow	29 (42.0)	23 (39.7)	
Green	39 (56.5)	34 (49.3)	
(Improved= 7, Deteriorated=4)			
Oral hygiene			
Red	12 (17.4)	11 (19.0)	*p*=.346
Yellow	13 (18.8)	6 (10.3)	
Green	44 (63.8)	41 (70.7)	
(Improved= 11, Deteriorated=4)			
Eye checks			
Red	11 (16.2)	15 (25.9)	*p*=.127 [a]
Yellow	7 (10.3)	2 (3.4)	
Green	50 (73.5)	40 (69.0)	
(Improved=9, Deteriorated=11)			
Feet check			
Red	30 (43.5)	8 (13.8)	***p*<.0001**[†]
Green	39 (56.5)	50 (86.2)	
(Improved=18, Deteriorated=1)			
Breast checks			
Red	42 (61.8)	22 (37.9)	***p*=.002**[†]
Green	26 (38.2)	35 (60.3)	
(Improved=14, Deteriorated=0)			
Menstrual cycle (female, n=40)			
Red	3 (7.9)	12 (33.3)	***p*=.021**[†]
Green	35 (92.1)	23 (63.9)	
(Improved= 1, Deteriorated=9)			
Smoking			
Red	24 (34.8)	19 (32.8)	*p*=1.000[†]
Green	45 (65.2)	39 (67.2)	
(Improved=1, Deteriorated=0)			
Physical activity			
Red	43 (62.3)	27 (46.6)	*p*=.847 [a]
Yellow	13 (18.8)	16 (27.6)	

Green (Improved=20, Deteriorated=8)	13 (18.8)	15 (25.9)	
Alcohol use			
Red	2 (2.9)	0 (0.0)	*p*=.157 [a]
Yellow	1 (1.4)	3 (5.2)	
Green (Improved=1, Deteriorated=1)	66 (95.7)	55 (94.8)	
Diet (fruit and vegetables)			
Red	1 (1.4)	1 (1.7)	***p*=.008[a]**
Yellow	21 (30.4)	9 (15.5)	
Green (Improved=13, Deteriorated=3)	47 (68.1)	48 (82.8)	
Diet (meat)			
Red	8 (11.8)	3 (5.2)	*p*=.827 [a]
Yellow	16 (23.5)	19 (32.8)	
Green (Improved=11, Deteriorated=10)	44 (64.7)	36 (62.1)	
Diet (rice)			
Red	5 (7.2)	3 (5.2)	***p*=.041[a]**
Yellow	28 (40.6)	18 (31.0)	
Green (Improved=16, Deteriorated=8).	36 (52.2)	37 (63.8)	
Caffeine intake			
Red	0 (0)	0 (0.0)	*p*=1.000 [a]
Yellow	3 (4.3)	3 (5.2)	
Green (Improved=2, Deteriorated=2)	66 (95.7)	55 (94.8)	
Fluid intake			
Red	3 (4.3)	0 (0.0)	***p*=.001[a]**
Yellow	16 (23.2)	6 (10.3)	
Green (Improved= 13, Deteriorated=1)	50 (72.5)	52 (89.7)	
Drug use			
Red	1 (1.4)	2 (3.4)	*p*=1.000[†]
Green (Improved=0, Deteriorated=1)	68 (95.7)	56 (96.6)	
Safe sex			
Red	6 (8.7)	0 (0.0)	*p*=.063[†]
Green (Improved=5, Deteriorated=0)	62 (89.9)	58 (100)	
Sexual functioning			
Red	1 (1.4)	2 (3.4)	*p*=1.000[†]
Green (Improved=0, Deteriorated=1)	68 (98.6)	56 (96.6)	
Bowels			
Red	11 (15.9)	5 (8.6)	*p*=1.000[†]
Yellow	0 (0.0)	2 (3.4)	
Green	58 (84.1)	51 (87.9)	

(Improved=7, Deteriorated=4)			
Urine problems			
Red	5 (7.2)	1 (1.7)	p=.250[†]
Green	64 (92.8)	57 (98.3)	
(Improved=3,Deteriorated=0)			
Regular health monitoring			
Red	11 (15.9)	5 (8.6)	p=.346[a]
Yellow	4 (5.8)	10 (17.2)	
Green	54 (78.3)	43 (74.1)	
(Improved=8, Deteriorated=10)			
Total Red flags (Mean, SD)	6.61 (2.99)	5.66 (2.48)	***p*=.005**[#], (Z=-2.81)
Total Yellow flags (Mean, SD)	3.56 (2.39)	3.15 (2.04)	p=.353[#], (Z= -0.93)
Total Green flags (Mean, SD)	20.16 (3.75)	21.64 (3.50)	***p*=.002**[#], (Z=-3.13)

^Some missing/unreported data at baseline and follow-up – valid percentages used

[†] McNemar test

[#] Wilcoxon signed rank test

[a] Friedman's two-way ANOVA – ordinal variables coded as: 1 (Green) no concern, 2 (Yellow) possible concern, 3 (Red) high concern.