Nurse-Facilitated Health Checks for Persons With Severe Mental Illness: A Cluster-Randomized Controlled Trial

Jacquie White, R.N., Ph.D., Joanne Lucas, B.Sc., M.Sc., Louise Swift, Ph.D., Garry R. Barton, M.Sc., Prof.Doc., Harriet Johnson, B.Sc., Clin.Psy.D., Lisa Irvine, B.A., Gabriel Abotsie, B.N., M.Sc., Martin Jones, R.N., Ph.D., Richard J. Gray, R.N., Ph.D.

Objective: This study tested the effectiveness of a nurse- delivered health check with the Health Improvement Pro- file (HIP), which takes approximately 1.5 hours to complete and code, for persons with severe mental illness.

Methods: A single-blind, cluster-randomized controlled trial was conducted in England to test whether health checks improved the general medical well-being of persons with severe mental illness at 12-month follow-up.

Results: Sixty nurses were randomly assigned to the HIP group or the treatment-as-usual group. From their case lists, 173 patients agreed to participate. HIP group nurses completed health checks for 38 of their 90 patients (42%) at baseline and 22 (24%) at follow-up. No significant between-group differ- ences were noted in patients' general medical well-being at follow-up.

Conclusions: Nurses who had volunteered for a clinical trial administered health checks only to a minority of participat- ing patients, suggesting that it may not be feasible to un- dertake such lengthy structured health checks in routine practice.

The impact of severe mental illness on mortality is marked. Life expectancy in a cohort of patients in London was reported to be reduced by up to 15 years among men and up to 18 years among women (1). Cardiovascular disease is the leading cause of mortality in this population (2). Prevalent risk factors for cardiovascular disease include cigarette smoking and obesity, leading to dyslipidemia, insulin re- sistance, and diabetes. Health checks are intended to identify current and anticipate future health problems and may contribute to enhancing patients' general medical well- being (3). Compared with patients who have other long-term conditions (for example, diabetes), patients who have severe mental illness are reported to have less frequent health checks and to receive health checks of inferior quality (4). A systematic review identified no relevant randomized con- trolled trials (RCTs) that established the effectiveness of general medical health monitoring for people with severe mental illness (5). A pilot RCT, which was published after this review was completed and which involved 12 nurses and 137 patients, found modest positive effects on the physical and mental well-being of patients who received a Chinese version of the Health Improvement Profile (HIP) (6).

The objective of this trial was to test the effectiveness of a structured 27-item nurse-delivered health check (the HIP), which takes approximately 1.5 hours to complete and code, on the general medical well-being of patients on their case list.

METHODS

A single-blind, cluster-randomized controlled trial was un- dertaken. Fieldwork was conducted between 2010 and 2014. Randomization was at the level of the nurse (cluster). The allocation ratio was 1:1. Participants were recruited from four National Health Service mental health trusts in the east of England. At the time of the study, health checks were not part of treatment as usual in participating trusts and were not a Commissioning for Quality and Innovation target. Nurses who were qualified for at least six months, who were working in adult community services, and who had at least five patients with severe mental illness on their case list were eligible to participate. Patients of participating nurses were eligible if they were over age 18, were considered able to provide informed consent, and had an *ICD-10* diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder. We excluded patients with a preexisting serious or unstable general medical condition and those who were pregnant or six months postpartum. Patients were also excluded if a clinician

determined that participation in the trial would put the patient, treating clinical team, or research team at risk.

Researchers presented the project at clinician team meet- ings and followed up with written information with nurses who were interested in participating. Subsequently, researchers arranged to meet with the nurses individually to discuss the study and seek their consent.

To minimize possible selection bias, we had intended to ask team leaders to screen participating nurses' caseloads to identify patients who may have met inclusion criteria. How- ever, they clearly indicated that they did not have capacity to do this, and we made a decision to amend the protocol and ask participating nurses to screen their own caseload. From this list, five patients were randomly selected. These patients were given information about the trial and were asked by their nurse whether they wanted to participate. Patients who expressed an interest were visited by a researcher, who followed a standard consent procedure. This process was repeated until five pa- tients per nurse were recruited, all eligible patients had been approached, or six weeks had elapsed from the date on which the first patient provided consent.

In both groups, patients received treatment as usual that includes psychiatric assessment and review, case manage- ment, psychotropic medication, and nursing care. At the time of the study general medical care was not an explicit part of standard treatment.

The HIP is a manualized approach to enhancing general medical well-being of patients with severe mental illness (7). Twenty-seven items address a range of health and lifestyle problems common in this population. Items are "flagged red" if the observation is outside the normal range. The nurse and patient are directed to evidence-based interventions that are incorporated into a care plan. The profile is to be completed annually and is anticipated to take no more than 1.5 hours to complete and code. The male and female versions of the HIP are available online (figshare.com/articles/Untitled_Item/5593861). Nurses in the HIP group received only three hours of ad- ditional training that was intended to enable them to complete health checks with the HIP (8). Training focused on common general medical comorbidities in severe mental illness; how to administer the HIP; and an overview of the manual, develop- ment of care plans, and signposting to additional resources.

The primary outcome was general medical well-being at 12-month follow-up determined by using the physical compo- nent subscale (PCS) of the 36-item Short Form Health Survey, version 2 (SF-36) (9). Possible PCS scores range from 0 to 100, with higher scores indicating better physical well-being. Harms monitoring involved recording serious adverse events (for ex- ample, death) reported at the 12-month follow-up assessment. Researchers, blind to group allocation, completed patient assessments at baseline and 12-month follow-up.

Our sample size calculation has been described in the trial protocol (8). In summary, we estimated that 50 nurses (25 in each group) would be required, each recruiting five patients from his or her case list. In total, we aimed to recruit 250 pa- tients (125 in each group).

Nurses were randomly assigned to either the HIP group or the treatment-as-usual group after patient recruitment was completed. The University of East Anglia Clinical Trial Unit undertook randomization by using procedures described in the trial protocol (8). The trial coordinators initiated ran- domization and then telephoned participating nurses to inform them of their group allocation. All other member members of the research team were blind to group allocation.

The trial received ethical approval from the Cambridge 4 Research Ethics Committee (10/H0305/73) and governance approvals from all participating NHS trusts. The trial was prospectively registered.

The effect of the HIP compared with treatment as usual was estimated by using mixed-effects models, including a random effect for nurse to allow for clustering, and adjusting for the baseline value of the outcome. Models were fitted by using Stata version 12.1 and restricted log likelihood. The prognostic value of each of 14 variables identified a priori in predicting the pri- mary outcome—SF-36 PCS score—was assessed, adjusting by baseline PCS score. Any potential covariate with $p_{\leq}.10$ was included in models to obtain adjusted estimates.

RESULTS

Of 198 nurses approached, 67 consented to take part in the study. Seven withdrew before randomization. Twenty-nine nurses (90 patients) were randomly assigned to the HIP group, and 31 nurses (83 patients) were randomly assigned to the treatment-as-usual group. [The trial CONSORT diagram and tables presenting data on nurse demographic characteristics, patient demographic and clinical characteristics, and details of serious adverse events are included in an online supplement to this report.] The baseline characteristics of nurses and patients in both groups (HIP and treatment as usual) were broadly similar. The mean6SD SF-36 PCS score was recorded at baseline and 12 months for 68 (76%) patients under the care of 25 nurses in the HIP group (baseline, 43.36610.97, and 12 months, 44.64612.47). The mean SF-36 PCS score was recorded at baseline and 12 months for 60 (72%) patients under the care of 24 nurses in the treatment-as-usual group (baseline, 44.07610.82, and 12 months, 43.80611.30).

Twenty-six of the 29 nurses (90%) assigned to the HIP group completed training. Nurses completed the HIP with 38 (42%) patients at baseline and 22 (24%) at follow-up. On average, it took 62 minutes (range 30 minutes to two hours 10 minutes) to complete the health check. For all but one patient, further nondirect patient contact time was spent completing the associated paperwork (mean=31 minutes; range 15 minute to one and one-half hours). The mean total time to complete the HIP and associated paperwork was one hour 33 minutes.

After adjustment for baseline score, the intervention effect was not significant in the intention-to-treat analysis. Mean follow-up scores on the SF-36 PCS were only 1.5 points higher for patients in the HIP group compared with the treatment- as-usual group (95% confidence interval=–1.5 to 4.5, p=.327,

intraclass correlation=.054). No significant effect (p=.511, intraclass correlation=.036) was found after adjustment for potential covariates showing a prognostic relationship with the primary outcome (number of medications and one or more first-generation antipsychotics).

We observed 38 serious adverse events over the course of this trial [see table in the online supplement]. A senior medical clinician investigated all adverse events according to the sponsor's standard operating procedures. None were considered related to participation in the trial.

DISCUSSION

The aim of this trial was to test the effectiveness of nurse-administered structured health checks (with a particular tool, the HIP) in improving the general medical well-being of patients with severe mental illness. Nurses motivated to agree to participate in a clinical trial might be expected to administer the health check instrument, yet fewer than half the health checks were completed at baseline. Consequently, we were unable to determine the effectiveness of using this health check tool (the HIP) in this population beyond noting the low uptake of instrument use, even by nurses who had volunteered to participate. We note that in contrast, authors of a similar trial in Hong Kong reported that nurses com- pleted health checks with all participating patients (6).

Recruitment of nurses and patients was not straightfor- ward. Of the 198 nurses approached to take part, only a third agreed. We also failed to recruit the required number of patients. Our observations may suggest that the feasibility of nurses' adopting a lengthy structured health check intended to enhance patients' physical health was low the from the outset. Team leaders were not willing to engage in recruitment of patients, and some were actively resistant to staff who expressed an interest in participating in the study. Since the conclusion of our trial, a qualitative study has highlighted reluctance among nurses to addresses the general medical health problems of this population (10).

The PCS measures patients' perception of their health status. Our decision to use the SF-36 PCS score as the primary outcome could be criticized as being too broad to detect subtle changes in health behaviors. It may not be sensitive enough (to change over 12 months) among indi- viduals with severe mental illness. More specific measures of health status, such as body mass index, were considered as alternatives but were rejected because they do not cap- ture the broad range of general medical health problems patients experience and the data are not routinely available for all patients.

Clustering in this trial was at the level of the nurse and not the team. It is a limitation that we did not address possible "contamination" (sharing the HIP) by nurses working in the same team but in different arms of the trial. We have no evidence that this occurred. Randomizing at the level of the team may have avoided this risk but would have required more sites to ensure a sufficient number of teams.

We were not able to control for the nonspecific effects of time spent training nurses and additional time nurses spent with patients completing the health check. We completed audits of a sample of patients' case notes to identify whether health checks were completed external to the study (for example, by the patient's psychiatrist). We found no evi- dence that this occurred.

In this trial, we sought to test the effectiveness of nurses undertaking health checks (that took about 1.5 hours to complete and code) for patients with severe mental illness. We did not first establish the feasibility of implementing the selected instrument, the HIP, to perform health checks in this population by nurses working in community services in England. Since the completion of this trial, health checks have been recommended as a part of standard care. How- ever, the tool that should be used and the length of time to complete and code are not specified. This has been done pragmatically rather than on the basis of empirical evidence. There remains a need for high-quality evidence to establish the feasibility and effectiveness of health checks in this setting for patients with severe mental illness.

The characteristics of nurses in the trial were represen-tative of those working in mental health services at that time. However, clinical practice has changed in the four years since the trial was completed. Our observations can probably be generalized to nurses working in community mental health services in England. However, nurses working in other parts of the world (notably Asia) may be more likely to complete health checks by using the HIP with this group of patients.

CONCLUSIONS

Nurses who had volunteered to participate in a clinical trial administered health checks only to a minority of the partici-pating patients on their case list, suggesting that the planned intervention, which consumed 1.5 hours per patient, was not feasible to implement in routine practice.

AUTHOR AND ARTICLE INFORMATION

Dr. White is with the Faculty of Health Sciences, University of Hull, Hull, United Kingdom. Ms. Lucas is with the Clinical Trials Unit, National Health Service (NHS) Blood and Transplant, Cambridge, United Kingdom. Dr. Swift, Dr. Barton, and Ms. Irvine are with Norwich Medical School, University of East Anglia, Norwich, United Kingdom. Dr. Johnson is with the Norfolk and Norwich Hospital University NHS Trust, Norwich. Mr. Abotsie is with Norfolk and Suffolk NHS Foundation Trust, Norwich. Dr. Jones is with the Department of Rural Health, University of South Australia, Wyalla, South Australia. Dr. Gray is with the Department of Nursing and Midwifery, La Trobe University School of Nursing and Midwifery, Melbourne. Send correspondence to Dr. Gray (e-mail: r.gray@latrobe.edu.au).

This article presents independent research commissioned by the Re- search for Patient Benefit Programme of the National Institute for Health Research (NIHR) (grant reference number PB-PG-1208-18122). Trial registration: Current Controlled Trials (ISRCTN 41137900). The authors thank all participants, the sponsor, the Public and Patient Involvement in Research members of the Steering Group, the database manager, and the 10 field researchers who worked tirelessly to implement the

protocol across four NHS sites. They also thank Katherine Dean for her supervision and mentorship of Dr. White. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health and Social Care.

Dr. White and Dr. Gray report receipt of honoraria and travel expenses from Janssen Pharmaceuticals UK and Otzuka Pharmaceuticals UK Ltd. The other authors report no financial relationships with commercial interests.

Received June 7, 2017; revisions received October 1, November 13, and December 9, 2017; accepted January 25, 2018; published online March 15, 2018.

REFERENCES

1. Chang C-K, Hayes RD, Perera G, et al: Life expectancy at birth for people with serious mental illness and other major disorders from a secondary mental health care case register in London. PLoS One 6:e19590, 2011
2. Hennekens CH, Hennekens AR, Hollar D, et al: Schizophrenia and increased risks of cardiovascular disease. American Heart Journal 150:1115–1121, 2005
3. Shuel F, White J, Jones M, et al: 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, 2010
4. Hardy S, Hinks P, Gray R: Screening for cardiovascular risk in patients with severe mental illness in primary care: a comparison with patients with diabetes. Journal of Mental Health 22:42–50, 2013
5. Tosh G, Clifton AV, Xia J, et al: Physical health care monitoring for people with serious mental illness. Cochrane Database of System- atic Reviews 1:CD008298, 2014
6. Bressington D, Chien WT, Mui J, et al: Chinese Health Improvement Profile for people with severe mental illness: a cluster-randomized, controlled trial. International Journal of Mental Health Nursing (Epub ahead of print, Aug 7, 2017)
7. Hardy S, White J, Gray R: The Health Improvement Profile: A Manual to Promote Physical Wellbeing in People With Severe Mental Illness. Keswick, Cumbria, United Kingdom, M&K Publishing, 2015. http://books.google.com/books?hl=en&lr=&id=kMV3CAAAQBAJ&oi=fnd&pg=PP1&dq=info:OplktdTBvQAJ:scholar.google.com&ots=MA4wFqkjVx&sig=iWlEtb2iojuhUrH_MhnLWnnfZuM
8. White J, Gray RJ, Swift L, et al: The serious mental illness Health Improvement Profile [HIP]: study protocol for a cluster randomised controlled trial. Trials 12:167, 2011
9. Ware JE Jr, Sherbourne CD: The MOS 36-item Short-Form Health Survey (SF-36): I. conceptual framework and item selection. Medical Care 30:473–483, 1992
10. Gray R, Brown E: What does mental health nursing contribute to improving the physical health of service users with severe mental illness? A thematic analysis. International Journal of Mental Health Nursing 26:32–40, 2017