

Health screening clinic to reduce absenteeism and presenteeism among NHS Staff: eTHOS a pilot RCT

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Scientific summary

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Scientific summary

Background

Staff sickness absenteeism and presenteeism (attending work while unwell) incur high costs to the NHS, are associated with adverse patient outcomes and have been exacerbated by the COVID-19 pandemic. The main causes are mental and musculoskeletal ill health with cardiovascular risk factors also common.

Objectives

The aim of this pilot trial was to assess the feasibility of a definitive randomised controlled trial (RCT) evaluating the clinical and cost effectiveness of a health screening clinic compared to usual care, in reducing sickness absenteeism and presenteeism amongst NHS staff.

The key objectives were to:

- describe recruitment rates
- describe participant characteristics and assess generalisability compared to the hospital workforce
- describe intervention screening assessment results
- describe recommended referrals and their uptake
- assess the feasibility of measuring the outcomes relating to the definitive trial, and obtain an estimate of the standard deviation of the proposed primary outcomes for a full RCT
- assess levels of contamination between intervention and usual care arms to inform RCT design (individual vs. cluster RCT)
- describe and explain the fidelity to the intervention and evaluate the barriers and enablers to participation
- describe the views, experiences and satisfaction of participants and those delivering the health checks
- quantify the costs of undertaking the screening service and its consequences.

Design

A multicentre, two-arm, parallel group, open-label, 1 : 1 individually randomised pilot RCT of a complex intervention comparing a staff health screening clinic with usual care.

Setting

Three large urban hospitals and one rural district general hospital in the West Midlands.

Participants

All employees in the participating hospitals were eligible to participate except those who had previously attended a pilot health screening clinic at Queen Elizabeth Hospital Birmingham (QEHB) or who were currently taking part in another non-COVID drug trial or similar health and well-being trial. Participants were informed of the trial through staff meetings, noticeboards, posters and ward champions, and invited (with up to three reminders) through multiple approaches including e-mail and personal invitation. Wards were chosen to reflect the characteristics of the hospital.

Data collection

Potential participants joined the trial via weblink to a custom-designed electronic trial data collection platform hosted by the Birmingham Clinical Trials Unit. Eligibility questions, consent and a baseline questionnaire were completed prior to randomisation.

Randomisation and blinding

Participants were randomised to intervention or usual care (1 : 1 ratio) using an integrated randomisation module on the trial database, using a minimisation algorithm (with random element) to ensure balance on key characteristics.

Interventions

Intervention

Staff health screening clinic with two stages: screening assessment for three components: mental health, musculoskeletal health and cardiovascular health, followed by appropriate advice and/or referral, according to level of risk, to appropriate services for management according to NHS/National Institute for Health and Care Excellence (NICE) recommendations. The screening assessment was delivered by trained research nurses using a standardised protocol. All data were captured by a customised database with prompts to guide the research nurses.

Local pathways were used for referrals to lifestyle, physiotherapy, psychological and primary care services. Participants reporting relevant conditions already being treated did not receive the referral element of that component. A results letter detailing findings and recommendations was sent to participants and their general practitioners (GPs) for appropriate action.

Usual care

Standard access to medical services for management of any presenting condition.

Main outcome measures

This pilot trial was originally planned to have a 52-week follow-up period to fully test the processes for a definitive trial, but this was reduced to 26 weeks due to the pandemic delays and funding restrictions.

Primary outcomes and stop/go criteria

Three coprimary outcomes were originally planned to inform progression to the definitive trial:

- *Recruitment* (consented) as a proportion of those invited.
- *Referral* to any recommended services as a result of the three screening components (usually GP, local physiotherapy/community psychological services) – *intervention arm only*.
- *Attendance* at any recommended services at 26 weeks (self-report) – *intervention arm only*.

We defined 'referral' as anyone who was *eligible* for a referral, that is they recorded a suitable risk value and were not already being treated for that condition.

Due to the pandemic, only a small number of participants completed the 26-week follow-up assessment. Therefore, acceptance of the referral (signifying intention), which was collected during the screening assessment, was used as a proxy for attendance.

The three coprimary outcomes formed stop/go criteria when considered together. If any of these values fell into the 'amber' zone, then the trial would require modifications to proceed to full trial. If all were 'red', then the trial would be considered unfeasible.

Secondary outcomes were collected to inform the design of the definitive RCT and any modifications required.

Secondary outcomes

- Comparison of baseline characteristics of included participants and hospital population.
- Description of intervention screening assessments results.
- Number/type of referrals to recommended services (intervention arm only).
- Attendance at each individual recommended service (intervention arm only).
- Lifestyle relevant to screening intervention advice and referrals (self-report at 26 weeks compared with baseline).
- Acceptability of intervention to participants and health screening clinic staff (interviews).
- Feasibility of trial processes (completeness of relevant data items, interviews).
- Indication of contamination (comparing pre/post data for health behaviours and health care/other service utilisation in control arm).

Outcomes related to the definitive trial

- Absenteeism at 26 weeks with reasons, measured by days and spells.
 - Self-reported absolute absenteeism, relative absenteeism and relative hours of work – for last 7 days and last 28 days [World Health Organization Health and Work Performance Questionnaire (WHO-HPQ)].
 - Self-reported absenteeism (6-month recall period).
 - Employee records of absenteeism, the proposed primary outcome of the definitive trial. Routinely collected linked data from the NHS Electronic Staff Record Programme.
- Presenteeism at 26 weeks [self-reported absolute presenteeism and relative presenteeism for last 28 days (WHO-HPQ)].
- Attendance at occupational health service at 26 weeks (self-report).
- Healthcare utilisation at 26 weeks (self-report) including GP consultations and hospital admissions.
- EuroQol-5 Dimensions, five-level version (EQ-5D-5L) index value measuring health-related quality of life (HRQoL) (EuroQol EQ-5D 5-level) at 26 weeks.
- Resource use and costs collected by self-report questionnaire to participants on health service utilisation and information from the screening assessment regarding duration and resources used.

Sample size

We aimed to recruit 480 participants (20 per week) in 24 weeks. With this sample size, the 95% confidence interval (CI) for the proportion of staff recruited could be estimated to be 4% either side of the estimate.

Statistical methods

Analyses were mainly descriptive. No statistical modelling was undertaken, and no *p*-values are reported. No subgroup analyses were planned.

Process evaluation

A mixed-methods process evaluation explored programme reach, fidelity of screening delivery, attendance at referrals and participants' views of the intervention to support any modifications required for the design of the definitive trial.

Quantitative data to support the process evaluation were obtained as above.

Semistructured *qualitative interviews/focus groups* were conducted (choice of Zoom, telephone, face-to-face) to obtain views of relevant stakeholders [trial participants, enhancing the Health of NHS Staff (eTHOS) nurses, referral providers, outside agencies] on the feasibility and acceptability of the staff

health screening intervention and trial and inform any protocol adaptations needed for a full trial. Due to the COVID-19 delays, a pragmatic approach was taken to sampling; all eligible participants in the intervention arm were invited to participate, and invitations were sent to all controls until the target number of participants had been reached.

Data were recorded either on Zoom or an encrypted recorder and transferred via secure file transfer to an external company for transcription. Interviews were transcribed intelligent/clean verbatim and anonymised. A thematic analysis of content was informed by the framework analytical approach. Data collection and analysis ran concurrently so that the emergent analytical themes could inform further data collection.

Health economic analysis

A descriptive analysis was presented with average costs of screening per participant and quality of life obtained in the baseline questionnaire. Information was obtained from participating centres on estimated time taken for each screening clinic task, grade of the member of staff responsible and cost of individual blood tests. Staff time required for each task was then multiplied by the relevant unit costs obtained from standard source. The total cost of blood tests per participant was weighted according to the proportion who received each type of blood test. Quality of life of all participants was estimated using the EQ-5D-5L.

Patient and public involvement

Four to six clinical, administrative and retired NHS staff met on a regular basis throughout the project to provide advice. One hospital healthcare worker was included on the Trial Oversight Committee (TOC). Similarly, we consulted a stakeholder advisory group representing a wider body of professionals relevant to the trial, for example, GPs.

Impact of COVID-19 pandemic on trial delivery

It was not possible to commence the trial in March 2020 due to the COVID-19 pandemic. Two hospital sites commenced the trial in December 2020, but after 3–4 weeks, recruitment was paused. The trial recommenced in May 2021 in all four sites. The original trial was planned to include a 52-week follow-up; however, due to the delays, a 26-week follow-up was agreed with the funder, but only a few people reached this time point before trial closure.

Results

Three thousand seven hundred and eighty-eight of the 24,344 NHS staff across the four sites were invited to take part. Of the 353 eligible respondents, 314 consented (8.3% of those invited and 65.4% of our planned target of $n = 480$). Two hundred and thirty-six were randomised into the study; $n = 118$ to the intervention screening arm and 118 to usual care. One hundred and one (85.6%) attended and completed the screening clinic. Only 26/236 (11.0%) participants reached the 26-week follow-up.

Primary outcomes and stop/go criteria

Three hundred and fourteen of the 3788 [8.3% (95% CI 7.4% to 9.2%)] invited staff gave their consent to participate, which meets *the red* stop/go criterion for *recruitment*.

Fifty-seven of the 118 [48.3% (95% CI 39.0% to 57.7%)] participants randomised to the intervention arm were eligible for referral to at least one service, which *meets the green* stop/go criterion for *referral*.

Eighteen of the 57 [31.6% (95% CI 19.9% to 45.2%)] participants eligible for a referral accepted a referral to at least one service, which *meets the amber* stop-go progression criterion for *attendance*, although the CIs were wide.

Secondary outcomes

Assessing generalisability (programme reach)

The *invited* population was similar to the hospital population, although those who *participated* in the trial were more likely to be white British (78.0% compared to 59.7%), allied health professionals (14.0% compared to 6.9%) and healthcare scientists (11.9% compared to 5.0%), and less likely to be from estates/ancillary, medical/dental and nursing/midwifery registered staff groups.

Results of intervention screening assessments

Most reported minimal/mild anxiety, but 11 (10.9%) were classified as having moderate and 5 (5.0%) severe anxiety. Most people reported minimal/mild depression, but 13 (12.9%) reported moderate/moderately severe depression and 4 (4.0%) severe depression.

Most participants had no significant back pain, although eight (7.9%) were at medium risk and two (2.0%) at high risk on the StarT Back tool. Twenty-seven (27.0%) scored with medium risk for other types of pain and five (5.0%) high risk.

Thirty-eight (38.0%) participants were classified as overweight and 32 (32.0%) obese. Forty-six (46.0%) were self-reported as physically active. Twelve (11.9%) reported increasing/higher risk of alcohol dependence and 10 (9.9%) were current smokers. Of those eligible for the cardiovascular risk score (QRISK2), nine (14.5%) had medium risk (10–19.9%) and two (3.2%) had a high risk of developing cardiovascular disease (CVD) in the next 10 years.

Completeness of data items and attendance at screening clinic (fidelity)

Sixty-six of the 314 (21.0%) consented participants did not complete the baseline questionnaire. One hundred and one of the 118 (86%) participants randomised to the intervention arm attended and completed the screening clinic. Individual data items were generally well completed and deoxyribonucleic acid (DNA) rates low.

Costs and quality of life

The maximum screening cost per participant (including blood tests) was £107.48 if the highest band staff were used and £99.98 if the lowest band staff ran the clinic. Complete EQ-5D-5L data were available for 233/236 randomised participants [mean score 0.793 (SD 0.168)].

Process evaluation

We conducted 51 (63.8%) out of the 80 originally planned interviews. Four different hospital sites utilised a nurse-led screening intervention with prompts and electronic data collection, which was efficient and promoted good fidelity, although this was viewed as impersonal at times. Participants appreciated the convenience of the onsite service and valued time to focus on their own needs. However, some felt that it did not reflect or address their stress levels appropriately or meet their expectations in providing faster access to additional services. There were also concerns that it would not address the wider determinants of ill health and problems in the workplace, that it was just a 'sticking plaster'. The eTHOS staff delivering the intervention generally found the delivery of the study feasible, although there were a number of suggestions from staff both delivering and receiving the intervention to adapt the approach for a full trial.

Conclusions

Despite significant delays, truncation and amendments required due to the COVID-19 pandemic, we were able to assess the most important aspects of the feasibility of a RCT to evaluate the clinical and cost effectiveness of a novel hospital-based staff health screening clinic in reducing absenteeism and presenteeism. Recruitment was feasible in a short space of time, and delivery of the intervention

feasible, efficient and acceptable. Although a lower *proportion* of staff were recruited than anticipated, this was offset by the findings of the screening assessments which revealed significant health needs of those attending with 48% requiring referral to additional services. The three stop/go criteria were red, green and amber; therefore, the TOC recommended that a full-scale trial should proceed, but with modifications (see below) to adapt to local context and adopt processes to engage better with underserved communities, to improve both reach and effectiveness.

Implications/modifications for full trial design

1. There was *no evidence of contamination*; therefore, an individual RCT would remain the design of choice. *Wait-list controls* might also be a potential option to encourage people to participate.
2. While our approach to recruitment was successful for many (most people responded to an e-mail), *additional strategies would be needed to recruit the underserved groups*, and specific minority staff network groups and leaders should be engaged in order to do so.
3. *Messaging to potential participants needs to be clearer* in order to reduce concerns about confidentiality, optimise recruitment and manage expectations.
4. More *flexible clinic times/alternative options* could be explored to improve inclusion.
5. *Electronic data capture was considered convenient*, but *extra training and practice* should be provided to ensure sufficient familiarity and personalisation.
6. Consideration (on a site-by-site basis) of *clearer referral pathways* is important for the full trial, in order to optimise attendance at referrals and realise health outcomes.
7. Further consideration should also be given to the *mental health screening tools* used, as qualitative interviews with staff revealed their concerns that occupational stress and burnout may not be adequately identified and treated.
8. There was *no evidence from this study that self-reported absenteeism data should replace human resources (HR) data* as the potential primary outcome as correlation between the two was poor.
9. Acknowledging the 25% dropout between consent and randomisation, the amount of data collected and *length of questionnaires should be reviewed* prior to a full trial.
10. *Resource use and cost data were relatively straightforward to collect*, although it was evident that *more detailed site-by-site data collection would be required* in a full trial, to reflect the full range of clinic organisation scenarios.

Trial registration

This trial is registered as ISRCTN10237475.

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