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Complementary effects of auricular acupressure in relieving constipation symptoms and promoting disease-specific health-related quality of life: A randomized placebo-controlled trial☆

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Summary
Objectives: Constipation has been identified as a worldwide health problem among elderly people. Currently, it is not effectively relieved by the use of laxatives and lifestyle modification. Previous studies reported promising results in managing constipation with auricular acupressure (AA), although its effectiveness was not affirmed. This study is to evaluate the complementary effects of AA in relieving constipation symptoms and in promoting disease-specific health-related quality of life (HRQOL) among elderly residential care home (RCH) residents in Hong Kong.
Design: Randomized placebo-controlled trial.
Setting: Elderly RCH.
Intervention: Ninety-nine participants were randomly assigned to either experimental group (AA using auricular plasters with magnetic pellets), placebo-controlled group (AA using auricular plasters with Semen Vaccariae), or usual care group (AA using auricular plasters only). AA was applied onto seven auricular acupoints for 10 days.
Main outcome measures: Constipation symptoms and disease-specific HRQOL were measured before AA, at the completion of AA (D10), and at the 10th-day follow-up time (D20).
Results: Significant group × time interaction effect was found in the change of satisfaction subscale between the experimental group and placebo-controlled group at D10 ($p = 0.016$) and D20 ($p = 0.016$) relative to the baselines. For both constipation symptoms and disease-specific

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HRQOL, the experimental group demonstrated the greatest improvement after receiving AA at both D10 and D20 compared with the other two groups.
Conclusion: The current findings indicated positive clinical value of AA with magnetic pellets in managing constipation in elderly RCH residents. AA was also found to be a safe and acceptable intervention.

Introduction

Constipation affects 25—40% of elderly people living in day hospitals or at home.[1] An even higher prevalence (59—73%) was reported among elderly people living in long-term health care settings.[1–3] In Hong Kong, the prevalence of constipation for the community-dwelling elderly people aged 65 years and older was 17.2% and for those 75 years and older was 22.8%.[4]

Elderly people suffering from constipation are more likely to be hospitalized when faecal impaction complicates the condition,[5] or they are prematurely admitted to long-term health care settings due to faecal incontinence.[6] Constipation also impairs the quality of life (QOL) of the sufferers.[7–10] Currently, constipation is generally managed by the use of laxatives and lifestyle modifications, both of which have presented contradictory findings regarding their effectiveness.[8,11–14] All these point to an imminent need for more effective strategies to manage constipation.

Auricular acupressure (AA) is a popular treatment modality in Chinese medicine. In AA, auricular stimulation can be achieved by tapping a small round object onto auricular acupoint. Based on the *Zangfu* and meridian theories, the auricle is in close relationship with other parts of the body that explain why AA can treat diseases in remote parts of the body.[15,16] AA is readily accepted in clinical practice because it is safe and convenient to manipulate together with positive therapeutic outcomes, but few undesirable effects have been reported.[17] The underlying principle behind AA in managing constipation is the regulation of the stomach and large intestine activities, as well as the circulation of *Qi* and blood, which results in an increase in intestinal peristalsis, thus generating a desire for defecation.[18]

Encouraging results have been reported in previous studies using AA in managing constipation in China, although no conclusion about its effectiveness can be made because of the poor methodological quality in these studies.[19] Therefore, this study was conducted to evaluate the complementary effects of AA in relieving constipation symptoms and in promoting disease-specific health-related QOL (HRQOL) among elderly residential care home (RCH) residents in Hong Kong.

Methods

Study design and participants

The study adopted a randomized placebo-controlled trial with pretest and repeated post-tests design. Participants were recruited according to the inclusion and exclusion criteria. The inclusion criteria recruited people who: (1) were of age over 65 and living in an RCH; (2) met the Rome III diagnostic criteria for constipation; the Rome III diagnostic criteria consider at least 12 weeks, not necessarily consecutive, in the past 12 months for two or more of the six criteria to exist for more than 25% of defecations. The six criteria include straining, lumpy or hard stools, sensation of incomplete evacuation, sensation of anorectal obstruction/blockage, application of manual manoeuvres and less than three defecations per week[20]; (3) were cognitively competent with a score $\geqq 6$ in the Abbreviated Mental Test[21]; and (4) were able to communicate in Cantonese. The exclusion criteria eliminated people who had local lesions/infection of the ears, or absence of ear(s); had prior experience of treatment with AA within one year of the study; were free from major physical and psychiatric diseases; were undertaking a bowel training programme; and had an implanted electrical device in the body to minimize the risk of affecting the normal functioning of the electrical device by the effects of magnetic pellets. All participants joined the study voluntarily and signed written informed consents. Ethical approval was obtained from the University ethical committee.

Random assignment and binding

The participants were assigned to either the experimental, the placebo-controlled group or the usual care group according to a computer-generated block randomization list. Block randomization has the advantage of keeping the number of participants randomly allocated to all study groups as close as possible[22] and avoiding an unacknowledged comparison between the late and early enrollees in an extended period of recruitment.[23] In this study, only the participants and the research nurse who was responsible for data collection were blinded to the participants' group assignments.

Intervention

As shown in Fig. 1, seven auricular acupoints, namely Large Intestine, Rectum, *San Jiao*, Spleen, Lung, Sympathesis, and Subcortex, were selected for AA because of their positive effects in relieving constipation symptoms.[16,19] Participants in the experimental group received AA using auricular plasters with magnetic pellets (the magnetic flux density of each magnetic pellet was approximately 200 Gauss); participants in placebo-controlled group received AA using auricular plasters with Semen Vaccariae; and participants in usual care group received AA using only auricular plasters. Placebo-controlled group served to balance the pressure effect of AA on the experimental group. The usual care group was included for comparison. Both magnetic pellet and Semen Vaccariae were of similar diameters (approximately 0.15 cm) to ensure the physical pressure exerted on the auricular acupoints by the taped objects was comparable. In addition, the auricular plaster was translucent adhesive tape of the same size (0.6 cm $\times$ 0.6 cm), colour, and texture for all participants to minimize the effect of perceived difference on