



A cluster-randomised controlled trial to test the efficacy of facemasks in preventing respiratory viral infection among Hajj pilgrims

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Abstract *Background:* Cost-effective interventions are needed to control the transmission of viral respiratory tract infections (RTIs) in mass gatherings. Face-masks are a promising preventive measure, however, previous studies on the efficacy of facemasks have been inconclusive. This study proposes a large-scale

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facemask trial during the Hajj pilgrimage in Saudi Arabia and presents this protocol to illustrate its feasibility and to promote both collaboration with other research groups and additional relevant studies.

Methods/design: A cluster-randomised controlled trial is being conducted to test the efficacy of standard facemasks in preventing symptomatic and proven viral RTIs among pilgrims during the Hajj season in Mina, Mecca, Saudi Arabia. The trial will compare the 'supervised use of facemasks' versus 'standard measures' among pilgrims over several Hajj seasons. Cluster-randomisation will be done by accommodation tents with a 1:1 ratio. For the intervention tents, free facemasks will be provided to be worn consistently for 7 days. Data on flu-like symptoms and mask use will be recorded in diaries. Nasal samples will be collected from symptomatic recruits and tested for nucleic acid of respiratory viruses. Data obtained from questionnaires, diaries and laboratory tests will be analysed to examine whether mask use significantly reduces the frequency of laboratory-confirmed respiratory viral infection and syndromic RTI as primary outcomes.

Conclusions: This trial will provide valuable evidence on the efficacy of standard facemask use in preventing viral respiratory tract infections at mass gatherings.

This study is registered at the Australian New Zealand Clinical Trials Registry (ANZCTR), ACTRN: ACTRN12613001018707 (<http://www.anzctr.org.au>).

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1. Introduction

Viral respiratory tract infections (RTIs), including influenza, are a major burden to public health. During any inter-pandemic year, there are an estimated 1 billion cases of influenza worldwide with 3–5 million cases of severe illness and 300,000–500,000 deaths [1]. Fear of the global spread of serious respiratory disease persists in the light of past pandemics, such as the severe acute respiratory syndrome (SARS), the influenza A (H1N1) pdm09 virus, and the recent emergence of the Middle East respiratory syndrome coronavirus (MERS-CoV) [2]. Ever-increasing international travel intensifies the risk of the spread of emerging novel viruses, further intensifying the concern [3]. Mass gatherings such as the Hajj pilgrimage pose a particular risk for transmission of respiratory viruses [4,5].

Health authorities require cost-effective measures that prevent or limit the global transmission of respiratory diseases. Facemasks represent a simple and cheap supplement to the use of hand-washing, antivirals, and vaccination in the control of viral RTIs.

Results from previous studies examining the effectiveness of facemasks have been either conflicting or inconclusive [6–17]. A randomised controlled trial (RCT) in a household setting found that adherence to facemask use decreased the risk of influenza-like illness (ILI) [7]. Meta-analysis of data from 6 trials shows that wearing facemasks is protective against ILI, but did not show that

facemasks are protective against laboratory-confirmed influenza, perhaps due to limitations of the studies (Fig. 1) [18]. Interestingly, one nested case–control study showed that intermittent facemask use was associated with a significantly greater risk of infection among healthcare workers at Hajj, suggesting perhaps that infectious material that settles on facemasks can become a source of direct hand transmission to the respiratory tract [19]. Standard facemasks may prevent: (i) acquisition of infection by droplet and/or aerosol spread, or conversely, (ii) transmission from infected subjects [20,21].

The major limitation of previous studies is their small sample size, and resulting lack of study strength to detect important, albeit moderate (e.g. 40–50%), protective effects of facemasks on laboratory-confirmed influenza or other infections [6,18]. The largest study undertaken to date was a cluster-randomised trial in 509 households, with 2788 recruits; it did not find an additional benefit from the combination of facemasks and hand hygiene over health education (regarding preventive measures) on the overall rate of laboratory-confirmed viral infection, although there was a benefit against secondary transmission of RTI and laboratory-confirmed influenza. The authors pointed to concerns about both under-powering of the study and poor compliance with mask use [11]. Bin Reza et al. recommended that sufficient power may be achieved by larger trials that are multi-centred and run for several years [6]. The authors of this study contend, in addition, that

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