Vaccine 31 (2013) 6003–6010

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

A cluster randomised controlled trial of a web based decision aid to support parents' decisions about their child's Measles Mumps and Rubella (MMR) vaccination☆

S. Shourie[a,1], C. Jackson[a,*], F.M. Cheater[a,2], H.L. Bekker[b], R. Edlin[b,3], S. Tubeuf[b], W. Harrison[c], E. McAleese[d], M. Schweiger[d], B. Bleasby[e], L. Hammond[f]

[a] School of Healthcare, University of Leeds, Leeds LS2 9UT, UK
[b] Leeds Institute of Health Sciences, University of Leeds, Leeds, LS2 9LJ, UK
[c] Leeds Institute of Genetics, Health and Therapeutics, University of Leeds, Leeds, LS2 9JT, UK
[d] West Yorkshire Health Protection Unit, Health Protection Agency, Leeds, LS15 7TR, UK
[e] NHS Leeds, Leeds, LS16 6QG, UK
[f] Parent representative, Leeds, UK

ARTICLE INFO

Article history:
Received 26 February 2013
Received in revised form 22 August 2013
Accepted 8 October 2013
Available online 19 October 2013

Keywords:
MMR
Measles
Decision aid
Decisional conflict
Leaflet

ABSTRACT

Objective: To evaluate the effectiveness of a web based decision aid versus a leaflet versus, usual practice in reducing parents' decisional conflict for the first dose MMR vaccination decision. The, impact on MMR vaccine uptake was also explored.
Design: Three-arm cluster randomised controlled trial. Setting: Fifty GP practices in the north of, England. Participants: 220 first time parents making a first dose MMR decision. Interventions: Web, based MMR decision aid plus usual practice, MMR leaflet plus usual practice versus usual practice only, (control). Main outcome measures: Decisional conflict was the primary outcome and used as the, measure of parents' levels of informed decision-making. MMR uptake was a secondary outcome.
Results: Decisional conflict decreased post-intervention for both intervention arms to a level where, parents could make an informed MMR decision (decision aid: effect estimate = 1.09, 95% CI −1.36 to −0.82; information leaflet: effect estimate = −0.67, 95% CI −0.88 to −0.46). Trial arm was significantly, associated ($p < 0.001$) with decisional conflict at post-intervention. Vaccination uptake was 100%, 91%, and 99% in the decision aid, leaflet and control arms, respectively (χ^2 (1, $N = 203$) = 8.69; $p = 0.017$). Post-hoc tests revealed a statistically significant difference in uptake between the information leaflet, and the usual practice arms ($p = 0.04$), and a near statistically significant difference between the, decision aid and leaflet arms ($p = 0.05$).
Conclusions: Parents' decisional conflict was reduced in both, the decision aid and leaflet arms. The decision aid also prompted parents to act upon that decision and, vaccinate their child. Achieving both outcomes is fundamental to the integration of immunisation, decision aids within routine practice. Trial registration: ISRCTN72521372.

1. Introduction

In England and Wales, the decline in MMR uptake following Wakefield's now discredited study [1] continues to reverse [2]. However uptake remains below the 95% target required for population immunity at 92% (1st dose by 24 months) and 88% (1st and 2nd dose by 5 years) [3]. The incidence of measles is at its highest for 18 years [4]. More widely, over 20 000 cases of measles were reported in 51 countries within the WHO European Region from January to October 2012 [5]. In the USA, where childhood immunisation is mandatory, 211 cases of measles were confirmed in 2011 the highest levels since 1996 [6]. These outbreaks are partially attributable to vaccine refusal [6,7] and strategies targeting different groups of parents

* Corresponding author. Present address: York Trials Unit, Department of Health Sciences, University of York, York, YO10 5DD, UK. Tel.: +44 0 1904 32 1869.
E-mail address: cath.jackson@york.ac.uk (C. Jackson).
[1] Present address: Monash Injury Research Institute, University of Monash, Melbourne 3800, Australia.
[2] Present address: School of Nursing Sciences, Faculty of Medicine and Health Sciences, Norwich Research Park, University of East Anglia, Norwich NR4 7TJ, UK.
[3] Present address: School of Population Health, Faculty of Medical and Health Sciences, University of Auckland, Private Bag 92019, Auckland, NZ.

0264-410X/$ – see front matter. Crown Copyright © 2013 Published by Elsevier Ltd. All rights reserved.
http://dx.doi.org/10.1016/j.vaccine.2013.10.025

who do not vaccinate their children continue to be needed [8,9].

Typically Government information about MMR vaccination, for example 'MMR the facts' [10], emphasises the risks of not having the vaccine with the aim of increasing uptake. Patient decision aids are a different type of information resource that provide detailed information on the probable risks and benefits of having *and* not having the MMR vaccination. Decision aids also encourage people to actively evaluate this information in accordance with their values, to make a decision [11]. Encouraging people to deliberate about their MMR beliefs may affect their motivation to vaccinate [12–14] hence their underuse in this context.

Few studies have evaluated decision aids for childhood immunisation decisions. In New Zealand, a childhood immunisation paper based decision aid reduced parent's anxiety about making the decision and encouraged promptness in vaccination [15]. An Australian MMR vaccination web based decision aid resulted in parents having more positive views towards MMR, feeling more informed and leaning towards vaccination [16]. This decision aid was subsequently adapted for UK parents and its feasibility evaluated [17]. The findings suggested that the decision aid may support both informed decision-making and vaccination uptake. Finally an MMR leaflet [18] was compared with the leaflet plus a community-based decision support intervention [19]. Parents in both groups felt more able to make an informed decision with those receiving the community intervention significantly more likely to take their child to be vaccinated. These studies suggest that interventions focusing on the decision-making process for MMR vaccination are associated with parents making informed decisions, and may also impact positively on vaccine uptake. However, with the exception of Jackson et al. [19], evaluations have used quasi-experimental designs and so cannot provide conclusive evidence of effectiveness.

This paper presents the findings from the first cluster randomised controlled trial to evaluate the effectiveness of a decision aid versus a leaflet versus usual practice for a childhood immunisation decision. Our primary interest was whether the decision aid compared with a leaflet could support parents' informed decision-making about the MMR vaccine. We were also interested in their impact on MMR uptake.

2. Materials and methods

This was a three-arm cluster randomised controlled trial: MMR decision aid plus usual practice, MMR leaflet plus usual practice and usual practice only (control). The study was approved by the York Ethics Committee (08/H1311/23), and registered on or about 31 October 2007 with the UK Clinical Research Network (UKCRN ID 4811) [20].

2.1. Participants and procedure

The UK childhood vaccination programme is administered primarily through primary care via General Practices (GPs). All 312 GP Practices within five Primary Care Providers (called Primary Care Trusts, PCTs) in the north of England were eligible to take part and offered £250 to participate. Uptake of first dose MMR ranged from 87% to 92% across the five PCTs at the time of the study [21]. First-time parents with a child aged 3–12 months being offered the first dose of the MMR vaccine were eligible. Parents were required to have an email address and sufficient English language skills to participate. On study completion, parents were offered a £10 gift voucher.

Eligible parents identified through GP practice registers were sent a postal invitation via their GP practice. Interested parents replied directly to the research team. Parents were then contacted by telephone (by SS, CJ) to confirm eligibility, enrol in the study and provide demographic data. The baseline questionnaire and consent form were subsequently sent to the parent. After all the baseline questionnaires had been sent out within a GP practice, that practice was randomised. On receipt of the completed baseline questionnaire and consent form, the appropriate intervention was delivered. At this point the researchers (SS, CJ) and participants were no longer blind to allocation. Only the statistician (WH) remained blind. The follow-up questionnaire was sent two weeks later. First dose MMR uptake data were collected from GP practices when children reached 15 months of age. Recruitment and follow-up occurred May 2009 to end September 2010.

2.2. Randomisation

Simple randomisation using a computer-generated random list allocated GP practices on a 1:1:1 basis. An independent researcher who had no contact with participants generated the allocation sequence and assigned the GP practices to their allocated arm.

2.3. Interventions

The interventions were delivered at the parent level.

2.3.1. MMR decision aid plus usual practice

Parents were posted the web link for the MMR decision aid and to reduce contamination risk were provided with a personal login to access it. They continued to receive usual practice (described below) from their GP practice. The decision aid was a modified version of the Australian MMR decision aid [16]. It can be accessed at www.leedsmmr.co.uk. Prior to this trial, it was assessed against the International Patient Decision Aids Standards [IPDAS, 22]. A description of the modified version, its adaptation and piloting is published elsewhere [17]. An overview is presented in Fig. 1.

2.3.2. MMR leaflet plus usual practice

Parents were sent the Health Scotland leaflet 'MMR your questions answered' [18] and received usual practice. Our previous research [19] found this leaflet to significantly reduce parents' decisional conflict. An overview is presented in Fig. 1. The leaflet does not meet IPDAS criteria [22] to be a decision aid.

2.3.3. Usual practice only (control)

Parents received the usual service provided by their GP practice. Parents of children registered with a GP are invited to have their child vaccinated for the first dose MMR at 12–13 months. Telephone interviews with participating GP practices indicated that usual practice typically included an appointment for the first dose MMR vaccination, a leaflet (usually 'MMR the Facts' [10]), and the offer of a consultation if the parent had concerns.

2.4. Measures

Demographic data were collected during the telephone contact as described above: date of birth, ethnicity, highest educational qualification, employment status, household income, sex and date of birth of the child.

Outcome data were collected at the individual parent level in the baseline and 2-weeks post-intervention questionnaires. Previously, we found two weeks was sufficient time for parents to utilise the resource they had been sent [19]. The baseline questionnaire is provided as supplementary material.

2.4.1. Primary outcome

Decisional conflict [23] assesses a parent's perception that their decision was informed, in accordance with their values, and can