Allergic Rhinitis Self-Management Program in Community Pharmacy

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EXECUTIVE SUMMARY

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The Pharmacy Guild of Australia manages the Fourth Community Pharmacy Agreement Research & Development which supports research and development in the area of pharmacy practice. The funded projects are undertaken by independent researchers and therefore, the views, hypotheses and subsequent findings of the research are not necessarily those of the Pharmacy Guild.
The Pharmacy Allergic Rhinitis Intervention Service (PARIS) project sought to test the findings of an earlier study which suggested that patients who received a structured, pharmacist-guided goal setting service for their AR experienced improved symptom severity and quality of life.

**Aims:**

The PARIS study aimed to implement a goal-setting model of intermittent allergic rhinitis (AR) self-management for use by Community Pharmacists and Pharmacy Assistants. Objectives were to:

(i) test a goal setting model of intermittent AR in a community pharmacy setting by comparing differences in outcome measures (AR-related quality of life, self-efficacy, symptom severity and adherence) of patients who received a goal setting model of intervention versus patients who received standard pharmacy care

(ii) investigate any seasonal differences in AR, and the goals that are set

(iii) evaluate the feasibility of the model

**Methods:**

An intervention versus control group, repeated measures designed trial was undertaken, utilising both quantitative and qualitative measures. Participants were sampled from the Sydney metropolitan area. purposive sampling of community pharmacies was undertaken first of all to ensure coverage of the Sydney basin, followed by random allocation of pharmacy staff to groups. Based on a power calculation, patient participant sample sizes were 160 per group (N=320).

Patient participant inclusion criteria for the study were: currently experiencing symptoms and having a previous history of intermittent AR; over the age of 18; and able to revisit the pharmacy in 10 days. Participants who had previously been in an AR study or self-management research conducted by the University of Sydney were excluded. Participants were also excluded if they were: pregnant, terminally ill, and/or showed symptoms not indicative of AR (e.g. sinus pain, loss of smell).

Pharmacists and Pharmacy Assistants received a ½ day training workshop on pathophysiology of intermittent AR, treatment and, for the intervention group, goal setting and strategy development. Both groups practised communications skills and the protocol delivery.

The study involved two visits: baseline (Visit1) and ten days post baseline (Visit 2). Data were collected on patient participant demographics, history of AR, medications, and measures of AR-related self-efficacy, quality of life, symptom severity and medication adherence. Two waves of data were collected: the first wave took place over Spring, 2008 and the second over Autumn, 2009.

Control group participants received standard pharmacy care, and they were required to keep a daily record of their perceived symptom severity scores and adherence to their AR medication. Intervention group participants also recorded these data, and were guided by the Pharmacist or Pharmacy Assistant to identify their symptoms and triggers and develop strategies to achieve the goals of ‘Eliminate/minimise hayfever symptoms’ and ‘Avoid/minimise hayfever triggers’. Space on the record card was provided for recording this information. Both groups of participants were required to return their record card at their second visit.

Data were also collected from Pharmacists and Pharmacy Assistants regarding who assisted the patient participants, the time it took to deliver the service and their views regarding recruitment, service delivery and the barriers and facilitators to implementing the service. A subset of patient participants (20%) was also interviewed following the completion of the study with respect to their views regarding the AR service. Costs relating to time, labour and service materials were also calculated as part of the evaluation of the service.

Data analyses comprised descriptive statistics, non-parametric tests to compare group outcome measure scores over time and multiple regression analysis to determine the extent to which variables of interest contributed to symptom severity scores. An ‘Intention to Treat’ calculation was also conducted. Chi-square statistics were calculated for proportional analyses. Thematic analyses of the qualitative interview data were undertaken to identify the types of strategies devised to control symptoms and triggers, and to identify the key issues important to pharmacy staff and patients regarding implementation of the service.

**Results:**

For the Spring data collection period a total of 22 Pharmacists and 16 Pharmacy Assistants participated in the study. Of these 80% committed to continuing the service for the Autumn phase which meant 19 Pharmacists and 12 Pharmacy Assistants participated. A total of 124 intervention group patient participants were recruited over the two data collection periods (Spring – 77; Autumn – 47) and 104 control group participants were recruited (Spring – 73; Autumn – 31) From the total of 228, eleven (11) patients withdrew from the study after visit 1.
Objective 1: At baseline, there were no significant differences between intervention and control groups on any measures (ps > 0.05). The average age of patient participants was 39 years. Female participants represented 65% of the total sample. Related illnesses included asthma, eczema and sinusitis. Patients reported an average of 4.5 symptoms (range 1-11) and 2.5 triggers (range 0-7). The most frequent AR symptom for both groups was nasal discomfort (eg congestion, itchiness, sneezing), followed by eye symptoms and physical discomfort. The most commonly reported triggers included plants, dust and changes in weather. The majority of patients had used antihistamines in the past to control their AR, Telfast being the most common.

At V1 almost twice as many intervention group participants purchased two or three medications (eg. antihistamine plus nasal spray or rinse) compared to control group participants, who were more likely to purchase just one (antihistamine).

Due to seasonal differences in some outcome measures of the Control Group, separate analyses were conducted for the Spring and Autumn data sets. Significant changes over time (ps < 0.01) were found for the Spring Intervention Group for all outcome measures. The Autumn Intervention Group participant scores were also significantly improved over time for self efficacy, symptom severity, quality of life and daily symptom severity (ps < 0.01). Adherence scores did not change significantly for this group over time. Change scores analysis revealed no significant differences between Intervention and Control Group scores for either season.

There were no differences in the outcomes of patients who received the service from a Pharmacist compared to a Pharmacy Assistant in the Intervention Group (ps > 0.05). Control group patients assisted by a Pharmacist had significantly higher quality of life and self-efficacy scores and significantly lower symptom severity scores compared to patients facilitated by a Pharmacy Assistant (ps < 0.05).

Multiple regression analyses were conducted to determine the extent to which participants’ V2 scores on medication taking, self efficacy, and quality of life contributed to V2 symptom severity scores. For each of these models, behavioural outcome measures (eg. quality of life; self efficacy; number of strategies devised to minimize AR triggers) were significant predictors of symptom severity. The extent to which participants took their antihistamine was a non-significant predictor of symptom severity in all cases.

Objective 2: Comparison of seasonal differences in symptoms, triggers and medications showed very similar findings (ps > 0.05), and mirror those reported for the combined intervention and control groups reported under Objective 1.

Comparison of strategies devised to control symptoms and triggers revealed that reinforcing medication adherence and dose information is potentially most useful when there is a need to control symptoms, and focusing on practical action is potentially most useful when controlling triggers.

Objective 3: Evaluation of the model’s feasibility showed strong endorsement by both pharmacy staff and patient participants. Pharmacy staff cited increases in confidence and communications skills, user-friendly protocol materials, increased partnerships between Pharmacist and Pharmacy Assistant, and ease of delivery of the service. All pharmacy staff in the intervention group took part in the evaluation. Twenty percent (20%) of patients were randomly selected to participate in the debrief interviews. The patient interviewees were a representative sample in terms of age and age at onset of AR. Gender and work status were slightly different to the total cohort (interviewees 72% female: cohort 63%) as was the number of interviewees at home (26%) compared to the cohort (15%) Patient participant satisfaction levels were high. Reported disadvantages included some time constraints (many of which were ameliorated by having trained Pharmacy Assistants to step in and deliver the service), difficulties in recruitment (particularly during Autumn) and engaging some patients in the self-management process.

The time taken to deliver a specialised service such as this was also relatively short – the average total time taken for V1 and V2 (excluding patient completion of questionnaires) was less than 15 minutes. The cost for delivering the service to 10 patients was estimated at $924. Assuming that participants would be willing to pay $25 for an annual PARIS service, and additional sales of medications would be an accrued benefit, possible income from delivering the service would be $550, leaving a net loss of $37.70 per patient. In an alternative scenario, where pharmacies opting to deliver the PARIS economised on input, it was possible to turn around the loss to a level of having a very modest profit of $2 per patient. Providing the service to a higher number of patients can possibly help achieve economies of scale.

Conclusions and Recommendations

The PARIS project was the first randomized controlled study in Australia designed to test the effect of a brief, tailored service through community pharmacies to patients with intermittent allergic rhinitis (AR). The service represented a move beyond existing models of standard pharmacy care, fostering instead a ‘therapeutic alliance’ between patient and pharmacy staff. The outcomes of the study demonstrate the potential of an intervention tool that can raise patient awareness of the condition and enhance self-management skills and confidence. In light of the prevalence of AR (~ 19%) and the population of patients that each pharmacy serves the results of this study
suggest that a simple and effective service with significant potential benefit to both patients and pharmacies can be implemented.

Pharmacy Assistants are often the initial point of contact for most S2/3 products in the pharmacy. The results of this study indicate that Pharmacy Assistants can be an integral part of the pharmacy team when delivering a specialized AR service to the community. In terms of providing management options for AR, Pharmacy Assistants are well positioned with respect to products, fewer time constraints as compared to pharmacists, and with knowledge and training this could significantly improve the type of practical advice that is given.

The results also suggest that medications alone are not always the most effective way to improve symptom severity. The data revealed that a wide range of practical advice strategies can be devised to minimize the triggers of AR. This represents a potentially new area in AR management for Pharmacists and Pharmacy Assistants to facilitate. In addition to providing medication strategies, strategies aimed at trigger avoidance and minimization can maximize effective management of AR; knowing what strategies to suggest to patients will improve the counselling skills of pharmacy staff and personalize the service.

On the basis of these outcomes it is recommended that:

- A service model of AR intervention be developed, based on either the control group protocol trialled in this study, or, preferably, the intervention protocol. The former model would involve provision of a brochure on AR aetiology, treatment and triggers and a wallet sized card to record symptom severity and medication taking. The latter model would involve additional counselling on identifying symptoms and triggers, strategy development, and recording on the card symptoms, triggers and strategies. The second option is recommended because of the opportunities for enhanced counselling on strategies and increased product purchasing potential.

- Training in the delivery of the service be provided. The resources, time and costs for this are not onerous given the scope of the service.

- Pharmacy Assistants be trained to deliver the service as well as Pharmacists.