Title Page

Costs and uptake of a community model of paediatric food allergy care versus specialist hospital care: a before-and-after controlled trial.

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Abstract

Aim: Compare the costs of community-based, food allergy model of care (Intervention Cohort, IC) to a tertiary hospital, specialist allergy clinic model of care (Control Cohort, CC).

Methods: In this pragmatic controlled trial, newly referred children (aged 0-12 years) to the Allergy Clinic at Melbourne's Royal Children's Hospital with suspected/known food allergy to three or less foods were allocated to see either a community-based paediatrician, trained via online webinars and web-based clinical decision support tools for food allergy diagnosis and management or a hospital allergist. Per patient costs to the healthcare system and out-of-pocket costs to families seen within 12 months (clinician time, allergy tests, Medicare billing) were compared between the two models of care.

Results: At 12 months, 54/181 (30%) CC families had been seen in the Allergy Clinic and 93/115 (81%) of the IC families who chose to see a community paediatrician had been seen. In an intention-to-treat analysis (ITT), healthcare system costs per IC patient were higher than per CC patient (mean cost \$333 versus \$319, respectively; mean difference \$14, 95% Confidence Interval (CI) -97 to 118, $p=0.81$). Total out-of-pocket costs to family were \$129 in the IC compared to \$89 in the CC (mean difference \$40, 95% CI \$4 to \$77, $p=.03$).

Conclusions: A community-based model of care for simple food allergy showed costs to the healthcare system were similar between the community model and hospital care but did not show reduced out of pocket costs to the families 12-months post-enrolment.

Key words: Food allergy care, model, community, paediatrician, children

What is already known on this topic:

- High prevalence of food allergy amongst Australian children and limited specialist allergy services based primarily at tertiary hospitals have resulted in waiting times in excess of 18 months for children with a suspected simple food allergy to access specialist allergy clinics.

What this paper adds:

- A new model of allergy care, delivered by trained community-based paediatricians, allows children with simple food allergy to be seen at no extra cost to the healthcare system.
- This community-based new model could provide an efficient means of managing children with simple food allergy.

Introduction

Prevalence of food allergies in the developed world has increased.^{1,2,3} Food allergies particularly affect children and can adversely impact their and their family's quality of life.⁴

In Australia, many children with food allergy are managed by allergy specialists in hospital settings. This has led to extended outpatient clinic waiting times for children with suspected food allergies to be assessed.⁵ As a result, parents may consider unproven alternatives to diagnose and manage food allergy which not only increases healthcare costs, but may also to misdiagnosis,⁶ an increased risk of adverse reactions from allergenic foods, or unnecessary child dietary restrictions.⁷⁻⁹

The diagnosis of food allergy relies on clinical history together with demonstration of allergen specific IgE (sIgE). sIgE may be detected by skin prick test or serum levels of sIgE (ssIgE) and both are applied in the clinical setting, either alone or together.¹⁰ Recent data have confirmed the reliability of ssIgE testing for the diagnosis of food allergies, paving the way for a decentralized model of care.¹¹

Based on a previous successful pilot¹², we conducted a large pragmatic trial comparing a community-based model of care for the management of simple (i.e. 3 or fewer foods) food allergy with standard specialist hospital-based care. We found that compared to hospital care, families who received community-based care were seen 10 months sooner, reported fewer anaphylactic reactions, and received care that was of comparable quality.¹³

In this paper we report on the healthcare system and family out-of-pocket costs of the community and hospital models of care at 12 months post-enrolment. We hypothesize that compared to specialist hospital-based care, costs to the healthcare system of the community care model would be lower but out-of-pocket costs to the family would be higher.

Methods

Design and Setting

Details of the trial methodology have been published.¹³ We compared a Control Cohort (CC) with an Intervention Cohort (IC). Families in the CC were recruited first and received standard hospital-based care based on skin-prick testing at the RCH Allergy Clinic. Families in the IC were recruited next and offered the opportunity to see a general paediatrician in the community. We invited community-based paediatricians with no formal allergy training and a practice within 20km of where children on the clinic waiting list resided (except for 12 families living in regional areas) to complete the Clinical Decision Support webinar training program and deliver care to IC families. Consultations with paediatricians are subsidized by the federal government's Medicare scheme and families may be charged variable out-of-pocket consultation fees depending on the doctor they see.

Eligibility and recruitment of families

A consecutive sample of children aged 0-12 years, newly referred to the RCH Allergy Clinic waiting list between 13 August 2015 to 22 March 2017 with suspected allergy to the following foods: peanut, soy, wheat, cow's milk, egg, shellfish, sesame, and tree nuts, were invited to take part. Children referred with suspected allergy to more than three foods, known or suspected anaphylaxis (based on referral letter or parent report at study intake interview), co-morbid severe eczema, or referred by a paediatrician for opinion were excluded, as were families with insufficient English to complete questionnaires.

Participants recruited between 2 September 2015 and 21 June 2016 received standard hospital-based care and formed the CC. Participants recruited between 22 June 2016 and 05 May 2017 formed the IC. The study was approved by the RCH Human Research Ethics Committee (HREC 35133). All families provided written informed consent.

Intervention

We have previously reported on our intervention and its outcomes.¹³ Briefly, three web-based Clinical Decision Support flowcharts (one each for IgE, non-IgE mediated food allergy and eczema) were designed by general paediatricians and allergists to cover nine key practice parameters common to published international guidelines.¹⁴⁻¹⁷ Each flowchart was accompanied by background information on key features to obtain on history and examination. Parent education materials were embedded as downloadable pdfs in each of the flowcharts. Community paediatricians were invited to complete training in the three one-hour webinars.

Post training, paediatricians conducted consultations with children in the IC based on the Clinical Decision Support flowcharts. They saw each child for an initial consultation with a follow up consultation if required.

For each consultation, allergists and community paediatricians were asked to complete a Consultation Record recording the child's diagnosis(es), management (including skin prick or sIgE testing), Medicare billing item, consultation start and finish time, and follow up including whether they referred the child back to the Allergy Clinic for an oral food challenge.

Standard hospital allergy clinic care

Clinicians working in the hospital Allergy Clinic typically saw the child once to take a history, examine the child, order SPTs where relevant, and formulate a diagnosis and management plan. SPTs were performed by a clinic nurse on the same day.

Outcome measures

Healthcare system costs

We calculated costs to the healthcare system for children who had received an allergy consultation by 12 months post-enrolment. Cost of allergy care included Medicare Benefits Schedule (MBS) item fees claimed for visits to community-based paediatricians and to hospital-based allergy specialists, the costs of the allergy tests and oral food challenges. Duration of visit to the community paediatrician was calculated from the Consultation Record. Time and motion data were collected from a sub-sample of 20 patients who attended the Allergy Clinic to estimate the total time spent with allergists and clinic nurses during clinic appointments. An average time per consultation was assumed for all families attending the clinic which included CC families and some IC families who had chosen not to see a community paediatrician.

Relevant unit costs were attached to recorded resource use (see Table 2) at each point of contact with a community paediatrician or Allergy Clinic to estimate a total cost for each study participant.

Costs to the family

In the baseline, 6 months and 12 months post-enrolment surveys, parents were asked to report on health service use and costs incurred for suspected food allergies including use of pharmaceuticals, alternative therapies and other health professional attendances for the

preceding 6-month period. As we are estimating the average out-of-pocket costs up to 12 months post-enrolment, we included the families completing both the 6 and 12 month surveys.

Total out-of-pocket costs to families were calculated using: travel distance to consultations and to have blood tests done; out-of-pocket costs for consultations and blood tests; time away from usual activities to attend consultations; purchasing of over-the-counter medicines (e.g. antihistamine, adrenaline auto-injectors); out-of-pocket costs incurred through the purchase of literature relating to the management of allergies; and out-of-pocket costs incurred through visits to health professionals, including GPs, paediatricians, allergy specialists and dietitians, allergy-related ED visits and inpatient admissions.

To calculate the costs associated with distances travelled, Government allowances of \$0.66 per km were applied to the reported travel distances. An hourly value for time away from usual activities was based on the Australian median annual salary (\$66,000), divided by the standard working hours per year (1,725) to generate a value of \$38.26.¹⁸ For over-the-counter medicines, unit costs were derived from the Pharmaceutical Benefits Schedule.¹⁹

Analysis

The primary analysis was by intention to treat (ITT) including all participants enrolled in the study within the cohort that they were recruited into regardless of whether they had been seen at the time of follow up. As a secondary analysis, we conducted a per protocol (PP) analysis where we excluded CC families who withdrew from the Allergy Clinic waitlist or failed to attend their appointment and IC families who chose not to see or failed to attend the paediatrician appointment.

For both the ITT and PP analyses, total costs for the CC and IC groups and average costs and consultation times per patient in each group were estimated over the 12-month period. The cost and time data were bootstrapped to generate 95% confidence intervals (CI) for each of the analysis outputs for the CC and IC group (due to the highly skewed nature of the cost data), as well as for the differences between the groups.

Results

Of the 994 children assessed for eligibility, 507 were eligible of whom 373 (74%) consented to take part. Of the 192 in the IC, 115 (60%) indicated they wanted to take up the community-based model of care with 93 of these patients (81%) doing so by 12 months. Of the 181 in the CC, 54 (28%) saw a hospital allergist by 12 months, 108 (60%) had not received an appointment at 12 months, and 19 had an appointment scheduled but failed to attend (11%). Overall sample retention at 6- and 12-months post recruitment was 325/373 (87%) and 317/373 (85%), respectively. Table 1 shows baseline characteristics of the IC and CC groups, by the ITT and PP analyses. IC families who chose to see the community paediatrician were similar to those who did not (all $P < 0.05$, Supplementary Table 1).

Twenty-six community paediatricians took part. The number of community paediatrician appointments attended by each IC child were one ($n=20$), two ($n=59$), or three ($n=2$). For 12 children, we were unable to determine the number of appointments because their Consultation Records were incomplete. Of the 93 children seen by a community paediatrician, 34 (37%) were referred back to the hospital by the paediatrician oral food challenge ($n=19$), possible anaphylaxis ($n=6$), SPT required ($n=4$) or other ($n=5$). Of the 19 referred for an oral food challenge, 7 (41%) were thought to need an oral food challenge by an RCH allergist.

Healthcare system costs

Table 3 reports the average cost and consultation time estimates per child seen for the two groups as well as the aggregate costs per group. In the ITT analysis, average costs per patient receiving allergy care were \$333 in the IC compared to \$319 in the CC (mean difference \$14, 95% CI -\$97 to \$118, $p=0.81$). The increased costs in the community model are due to follow-up paediatrician visits and the costs of the 29 families who waited and were seen in the Allergy Clinic. In the PP analysis however, average costs per patient was slightly lower in the community model (\$284 for the IC versus \$319 for the CC; mean difference -\$35 (95% CI -\$156 to \$62), $p=0.54$).

For the ITT analysis, total healthcare system costs across the IC were \$49,973 compared to \$17,213 in the CC; difference \$28,759 (95% CI \$19,805 to \$39,400, $p<0.0001$), reflecting increased access to health services in the IC.

Family out-of-pocket costs

In the ITT analysis, the total out-of-pocket costs per family was \$129 in the IC compared to \$89 in the CC (mean difference \$40, 95% CI \$4 to \$77, $p=.03$, Table 4). In the PP analysis, the difference in total out-of-pocket cost per family was higher (\$171 for the IC versus \$73 for the CC; mean difference \$98, (95% CI \$58 to \$138), $p<.0001$).

Costs relating to time away from usual activities (productivity losses) were also higher in the IC. In the ITT analysis, IC losses equated to \$389 compared to \$339 in the CC (mean difference \$50, 95% CI -\$115 to \$215, $p=.55$). In the per protocol analysis, losses to the value of \$379 were estimated for the IC compared to \$304 in the CC (mean difference \$75, 95% CI -\$84 to \$234, $p=0.35$).

Discussion

This is the first study to evaluate the costs of a community-based model of care for simple paediatric food allergy based on sIgE. In the ITT analysis, there was a greater overall mean cost to the healthcare system per patient seen, higher out-of-pocket costs to the family and higher productivity losses in the IC versus CC. However, when the analysis was restricted to those families who received their allocated intervention (PP analysis), there was a lower mean cost to the healthcare system in the IC versus CC but the total out-of-pocket and productivity costs were higher in the IC (although neither reached statistical significance). Based on the costs to the healthcare system, this suggests that community-based care provides an efficient means to deliver timely care for simple food allergy with minimal increased costs to families. We could find no other evaluations of models that aim to shift simple food allergy care from over-burdened hospital systems.^{14, 15} Hence our study provides important and novel information on the costs of such a model and addresses a major issue in healthcare access for children with food allergy.

To implement a community model of care for managing simple food allergies, triaging of children with suspected simple food allergy away from hospital services to a trained community paediatrician would need to occur. Such triaging raises issues around equity of care and parent rights to choose where their child is treated. Whilst some community paediatricians in Victoria bulk bill (six of 26 did so in this study), many do not. As a result, families may have to pay an out-of-pocket cost to see a community-based paediatrician for a service, which would not be incurred in the public hospital system. In this trial, we told families about potential out-of-pocket costs and despite this, 60% of eligible families chose to see the community paediatrician. This percentage could rise with active re-direction of referrals but such re-direction would need to consider family preference and ability to pay. Some Australian paediatric hospital allergy clinics already actively re-direct referrals for children with suspected simple food allergies back to their primary care providers.²⁰

Within the IC, 34 families were referred back to the allergy clinic; 19 for a possible oral food challenge. This undermines the efficacy of the model. However, of these, only seven went on

to have an oral food challenge. Further research is needed to understand why this is so (e.g. lack of clarity about when a challenge is/is not needed, variation in individual allergist care) and changes to training or guidelines may be required to reduce what seemed to be some unnecessary referrals back to the hospital.

This study has several strengths. We had a large sample, good clinical engagement with community paediatricians, comprehensive cost data, high retention rates and little missing data. A limitation was that families were not randomly allocated to groups so potential unmeasured confounders could be unequally distributed between groups. In a pragmatic trial such as this, we could not use a parallel design because doing so would artificially reduce the time to be seen (our primary outcome) in the CC as we would have recruited our intervention sample from the waitlist, therefore reducing the length of the waitlist. Nevertheless, baseline sociodemographic and child atopy characteristics were broadly similar between the two groups. We could not blind families to their group status, but this is unlikely to have affected the costs of care as these are largely beyond the family's influence. The 12-month time horizon limited the capture of longer-term cost differences between children in the IC and CC groups and our results may not generalize to families attending appointments after this period. We only studied one model of food allergy care and further research could examine costs of food allergy care delivered by private specialists. Finally, our results may not generalize to non-English speaking families.

Implications for clinical practice or health policy

Published results of our trial provide evidence that community-based paediatricians offer care sooner that is of similar quality and safety to that provided by their allergy specialist counterparts.¹³ This economic analysis suggests that the new model could provide an efficient means of managing simple paediatric food allergy care. Ultimately, some care for less complex food allergy could be de-centralized from tertiary specialists to community paediatricians which will require triaging of hospital referrals and training of community

paediatricians. This in turn could shorten tertiary centre waiting lists and free up these centres to manage more complex food allergy.

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Table 1. Baseline characteristics of participants, by intention-to-treat and per protocol analysis

		Intention to treat (all families)		Intention to treat (seen by 12 months)		Per (all
Characteristics		Intervention (n=192) n (%)	Control (n=181) n (%)	Intervention (n=123) n (%)	Control (n=54) n (%)	Intervention (n=93) n (%)
Child	Age in years, <i>M</i> (<i>SD</i>)	3.7 (2.8)	3.4 (2.9)	3.8 (3.0)	2.0 (2.3)	4.2 (3.1)
	Male,	113 (58.9)	95 (52.5)	75 (61.0)	30 (55.6)	59 (63.4)
	1 st child	95 (49.5)	95 (52.5)	64 (52.0)	30 (55.6)	43 (46.2)
	Health care card	54 (28.1)	51 (28.2)	31 (25.2)	10 (18.5)	21 (22.6)
Child's condition	Number of known/suspected food allergies:					
	1	108 (56.3)	115 (63.5)	72 (58.5)	37 (68.5)	54 (58.1)
	2	54 (28.1)	53 (29.3)	34 (27.6)	14 (25.9)	26 (28.0)
	3 or more	30 (15.6)	13 (7.2)	17 (13.8)	3 (5.6)	13 (14.0)
	Suspected/known allergens:					
	Peanut	96 (50.0)	80 (44.2)	63 (51.2)	23 (42.6)	50 (53.8)
	Tree nuts	64 (33.3)	57 (31.5)	40 (32.5)	9 (16.7)	34 (36.6)
	Egg	60 (31.3)	64 (35.4)	39 (31.7)	27 (50)	22 (23.7)
	Cow's milk	33 (17.2)	32 (17.7)	19 (15.5)	12 (22.2)	17 (18.3)
	Other	26 (13.5)	16 (8.8)	11 (8.9)	3 (5.6)	7 (7.5)
	Previous diagnoses:					
	Eczema	123 (64.1)	111 (61.3)	76 (61.8)	34 (63.0)	57 (61.3)
	Hay fever [*]	33 (17.2)	33 (18.2)	19 (15.5)	7 (13.0)	17 (18.3)
	Asthma [†]	41 (21.4)	37 (20.4)	25 (20.3)	8 (15.0)	22 (23.7)
Family characteristics	English main language in the home	144 (75.0%)	144 (79.6%)	94 (76.4)	43 (79.6)	71 (76.3)
	Socio-economic status (SEIFA [‡]) <i>M</i> (<i>SD</i>)	1010.7 (53.6)	1016.1 (55.8)	1003.8 (58.4)	1020.9 (53.14)	1001.4 (61.1)

	Family member with medical conditions:					
	Food allergy	57 (29.7)	59 (32.6)	27 (22.0)	16 (29.6)	18 (19.4)
	Eczema	94 (49.0)	82 (45.3)	55 (44.7)	23 (42.6)	41 (44.1)
	Hay fever [§]	117 (60.9)	121 (66.9)	78 (63.4)	33 (61.1)	59 (63.4)
	Asthma [†]	81 (42.2)	77 (42.5)	55 (44.7)	21 (38.9)	43 (46.2)
Responding parent	Age in years <i>M</i> (<i>SD</i>) [¶]	36.1 (5.7)	36.2 (5.7)	36.1 (5.9)	36.2 (5.7)	36.5 (6.1)
	Mother ^{**}	166 (86.5)	165 (91.2)	105 (85.4)	51 (94.4)	79 (85.0)
	Has cohabiting partner	175 (91.2)	166 (91.7)	116 (94.3)	50 (92.6)	88 (94.6)
	Highest education:					
	Completed University Qualification ^{††}	113 (58.9)	124 (68.5)	70 (56.9)	37 (68.5)	54 (58.1)

* 1 missing value from the ITT IC (all families), 3 missing values from the ITT CC (all families), missing value from ITT IC (seen by 12 months), 1 missing value from PP IC (all families), 1 missing value from the PP CC (all families), 1 1 missing value from PP IC (seen by 12 months).

[†] 2 missing values from the ITT CC (all families), 1 missing value from the PP CC (all families).

[‡] SEIFA (Socio-Economic Indexes for Areas) was developed by the Australian Bureau of Statistics to rank areas in Australia by relative socio-economic disadvantage, based on the 5-yearly Census data. Mean=1000, SD=100²¹.

[§] 1 missing value from the ITT IC (all families), 1 missing value from the ITT IC (seen by 12 months).

[†] 1 missing value from the ITT IC (all families), 2 missing values from the ITT CC (all families), 1 missing value from the ITT IC (seen by 12 months), 1 missing value from the PP IC (all families), 1 missing value from the PP CC (all families).

[¶] 3 missing values from the ITT IC (all families), 2 missing values from the ITT CC (all families), 2 missing values from the PP CC (all families).

^{**} 1 missing value from the ITT CC (all families), 1 missing value from PP CC (all families).

^{††} 1 missing value from the ITT IC (all families).

Abbreviations: ITT, intention to treat, PP, per protocol, CC, Control cohort, IC, Intervention cohort

Table 2. Unit costs

Resource	Unit cost (\$)
Initial attendance (<45mins) MBS Item 110*	128.3
Initial attendance (>45mins) MBS Item 132*	224.35
Subsequent attendances (<20mins) MBS Item 116*	64.2
Subsequent attendances (<20mins) MBS Item 133*	112.3
Skin prick test (hospital)	33.15
sIgE test (community)	22.8
sIgE test (hospital)	22.8
Ara h2 test (hospital)	22.8
Oral Food Challenge	1150

* MBS Item unit costs reflect 85% of the full MBS Item benefits

Abbreviations: MBS, Medicare Benefits Schedule, sIgE, serum specific immunoglobulin E.

Table 3. Cost to the Healthcare system for children seen by 12 months

	Intention to treat analysis				Per protocol analysis			
	Intervention Cohort (n=123) 30: allergy clinic visit	Control Cohort (n=54)	Difference (IC – CC)	P value	Intervention Cohort (n=93) of whom 31 referred and seen in allergy clinic	Control Cohort (n=54)	Difference (IC – CC)	P value
Time (mins) spent per patient seen (95% CI)*	73 (69 to 78)	111 (97 to 126)	-38 (-49 to -27)	<0.0001	63 (59 to 66)	111 (97 to 126)	-49 (-63 to -35)	<0.0001
Costs per patient (\$) (95% CI) for:								
SPT (community) SPT (hospital) [†]	1.0 (0 to 3) 13 (11 to 16)	31 (29 to 33)	-16 (-20 to -13)	<0.0001	2 (0 to 3) 9 (6 to 11)	31 (29 to 33)	-21 (-24 to -17)	<0.0001
sIgE test (community) sIgE test (hospital)	14 (13 to 16) 1.0 (0.3 to 1.8)	1.3 (0.0 to 3)	14 (12 to 16)	<0.0001	18 (16 to 20) 1.0 (0.2 to 2.1)	1.3 (0.0 to 3.0)	18 (15 to 20)	<0.0001
ARA h2	0 (0 to 1)	0 (0 to 1)	0 (-1 to 1)	0.85	0 (0 to 0)	0 (0 to 1)	0 (-1 to 0)	0.19
Oral Food Challenge	78 (25 to 150)	106 (22 to 217)	-28 (-135 to 77)	0.62	11 (0 to 32)	106 (22 to 217)	-95 (-217 to 0)	0.08

MBS Item fees (comm.) [‡]	184 (174 to 195)	179.8 (167 to 193.5)	5 (-7 to 17)	0.47	236 (222 to 250)	179.8 (167 to 193.5)	56 (42 to 70)	<0.0001
MBS Item fees [§] (hospital)	66.9 (55.3 to 78.6)				41.7 (27.6 to 55.5)			
Average costs (\$ per/patient seen (95% CI)	333 (270 to 414)	319 (225 to 430)	14 (-97 to 118)	0.81	284 (250 to 324)	319 (225 to 430)	-35 (-156 to 62)	0.54
Total costs (\$) in 12 months (95% CI)	45,973 (37,238 to 57,167)	17,213 (12,168 to 23,216)	28,759 (19,805 to 39,400)	<0.0001	30,661 (26,996 to 34,970)	17,213 (12,168 to 23,216)	13, 448 (6,141 to 19,980)	<0.001

* assuming patients referred to the RCH by a community paediatrician had an average contact of 111 minutes (as observed for other patients attending the RCH).

[‡] 1 missing value from the ITT CC, 1 missing value from the PP CC.

[‡] 5 missing values from the ITT IC, 5 missing values from the PP IC.

[§] 1 missing value from the ITT CC, 1 missing value from the ITT IC, 1 missing value from the PP IC, 1 missing value from the PP CC.

Abbreviations: ITT, intention to treat, PP, per protocol, CC, Control cohort, IC, Intervention cohort

Table 4. Out of pocket costs to the family within 12 months

	Intention to treat analysis				Per protocol analysis			
	Intervention Cohort (n=163)	Control Cohort (n=135)	Difference (IC – CC)	p value	Intervention Cohort (n=82)	Control Cohort (n=121)	Difference (IC – CC)	P value
Average (mean) costs per patient (\$) at 12 months (95% CI) for:								
Study visits								
Paediatrician Visits OOP	49.2 (34.2 to 64.3)	0	49.2 (32.8 to 65.7)	<0.0001	86.7 (60.1 to 113.3)	0	86.7 (65 to 108.3)	<0.0001
Community Blood tests OOP	2 (0.3 to 3.6)	0	2 (0.2 to 3.8)	0.03	4 (0.7 to 7.2)	0	4 (1.3 to 6.6)	0.004
Total visits OOP (visit and blood tests OOPs)	51.2 (35.9 to 66.6)	0	51.2 (34.4 to 68.1)	<0.0001	90.7 (63.5 to 117.7)	0	90.7 (68.6 to 112.7)	<0.0001
Travel to visit & blood tests OOP*	21.3 (17.1 to 25.5)	7.4 (4.6 to 10.3)	13.9 (8.6 to 19.2)	<0.0001	31.1 (24.3 to 38)	8.3 (5.1 to 11.5)	22.8 (16 to 29.6)	<0.0001
Total visit OOP[†]	72.5 (56.1 to 89)	7.4 (4.6 to 10.3)	65.1 (46.9 to 83.3)	<0.0001	121.8 (94.1 to 149.4)	8.3 (5.1 to 11.5)	113.4 (90.6 to 1336.3)	<0.0001
Other services accessed								
GP OOP [‡]	1.8 (0.4 to 3.1)	3 (1 to 5)	-1.2 (-3.6 to 1.1)	0.30	0.4 (0 to 1.2)	3 (0.9 to 5.2)	-2.6 (-5.3 to 0)	0.05

Paediatrician OOP	5.8 (0.8 to 10.7)	6.3 (0.4 to 13)	-0.5 (-8.7 to 7.6)	0.90	5.2 (0 to 11.8)	6.2 (0 to 13.6)	-1 (-11.4 to 9.4)	0.85
OTC OOP	23.4 (19 to 27.8)	16.5 (12.9 to 20.2)	6.9 (1.0 to 12.7)	0.02	24.8 (18.6 to 31)	15.6 (12 to 19.3)	9.2 (2.5 to 15.9)	0.01
Other services accessed OOP [§]	25.9 (10.7 to 41)	55.8 (31.3 to 80.3)	-29.9 (-2.2 to -57.6)	0.03	18.5 (0.6 to 36.5)	39.5 (17.9 to 61.1)	-21 (-51 to 9)	0.17
Total OOP of all other services accessed	56.8 (38 to 75.6)	81.6 (54.9 to 108.3)	-24.8 (-56.6 to 7)	0.49	49 (29.5 to 68.4)	64.4 (41.2 to 87.7)	-15.4 (-47.7 to 16.9)	0.35
TOTAL OOP	129.4 (104.3 to 154.5)	89.1 (62.5 to 115.7)	40.3 (3.8 to 76.8)	0.03	170.7 (135.9 to 205.6)	72.7 (49.5 to 95.9)	98 (58.1 to 138)	<0.0001
Parents "days off" to attend visits ^{**}	152.9 (116.4 to 189.4)	70.8 (40.7 to 100.9)	82.1 (33.7 to 130.4)	0.001	209.6 (152.4 to 266.8)	79 (45.7 to 112.3)	130.6 (69 to 192.2)	<0.0001
Parents "days off" to attend other services	236.1 (132.3 to 334)	268.4 (156.8 to 380)	-32.3 (-184.4 to 120)	0.68	169.8 (73.8 to 264.7)	225.1 (136.1 to 314.1)	-55.3 (-188.5 to 77.8)	0.41
Total productivity losses	389 (273.8 to 504.2)	339.2 (222.2 to 456.3)	49.8 (-115 to 214.6)	0.55	379.4 (250.5 to 508.3)	304.1 (205.7 to 402.6)	75.3 (-83.6 to 234.1)	0.35

* 2 missing values from the ITT IC, 1 missing value from the PP CC.

† 3 missing values from the PP CC.

‡ 1 missing value missing value from the ITT IC, 5 missing values from the PP CC.

§ 2 missing values from the PP CC.

|| 2 missing values from the PP CC.

¶ 3 missing values missing value from the ITT IC, 8 missing values from the PP CC.

** 2 missing values from the PP CC.

Abbreviations: OOP, out of pocket; OTC, over the counter; ITT, intention to treat; PP, per protocol; CC, Control cohort; IC, Intervention cohort

Table 1. Baseline characteristics of participants, by intention-to-treat and per protocol analysis

		Intention to treat (all families)		Intention to treat (seen by 12 months)		Per protocol (all families)		Per protocol (seen by 12 months)	
Characteristics		Intervention (n=192) n (%)	Control (n=181) n (%)	Intervention (n=123) n (%)	Control (n=54) n (%)	Intervention (n=93) n (%)	Control (n=157) n (%)	Intervention (n=93) n (%)	Control (n=54) n (%)
Child	Age in years, <i>M (SD)</i>	3.7 (2.8)	3.4 (2.9)	3.8 (3.0)	2.0 (2.3)	4.2 (3.1)	3.4 (3.1)	4.2 (3.1)	2.0 (2.3)
	Male,	113 (58.9)	95 (52.5)	75 (61.0)	30 (55.6)	59 (63.4)	79 (50.3)	59 (63.4)	30 (55.6)
	1 st child	95 (49.5)	95 (52.5)	64 (52.0)	30 (55.6)	43 (46.2)	81 (51.6)	43 (46.2)	30 (55.6)
	Health care card	54 (28.1)	51 (28.2)	31 (25.2)	10 (18.5)	21 (22.6)	43 (27.4)	21 (22.6)	10 (18.5)
Child's condition	Number of known/suspected food allergies:								
	1	108 (56.3)	115 (63.5)	72 (58.5)	37 (68.5)	54 (58.1)	96 (61.2)	54 (58.1)	37 (68.5)
	2	54 (28.1)	53 (29.3)	34 (27.6)	14 (25.9)	26 (28.0)	50 (31.9)	26 (28.0)	14 (25.9)
	3 or more	30 (15.6)	13 (7.2)	17 (13.8)	3 (5.6)	13 (14.0)	11 (7.0)	13 (14.0)	3 (5.6)
	Suspected/known allergens:								
	Peanut	96 (50.0)	80 (44.2)	63 (51.2)	23 (42.6)	50 (53.8)	74 (47.1)	50 (53.8)	23 (42.6)
	Tree nuts	64 (33.3)	57 (31.5)	40 (32.5)	9 (16.7)	34 (36.6)	48 (30.6)	34 (36.6)	9 (16.7)
	Egg	60 (31.3)	64 (35.4)	39 (31.7)	27 (50)	22 (23.7)	55 (35.0)	22 (23.7)	27 (50)
	Cow's milk	33 (17.2)	32 (17.7)	19 (15.5)	12 (22.2)	17 (18.3)	29 (18.5)	17 (18.3)	12 (22.2)
	Other	26 (13.5)	16 (8.8)	11 (8.9)	3 (5.6)	7 (7.5)	12 (7.6)	7 (7.5)	3 (5.6)
	Previous diagnoses:								
	Eczema	123 (64.1)	111 (61.3)	76 (61.8)	34 (63.0)	57 (61.3)	101 (64.3)	57 (61.3)	34 (63.0)
	Hay fever*	33 (17.2)	33 (18.2)	19 (15.5)	7 (13.0)	17 (18.3)	29 (18.5)	17 (18.3)	7 (13.0)

	Asthma [†]	41 (21.4)	37 (20.4)	25 (20.3)	8 (15.0)	22 (23.7)	31 (19.8)	22 (23.7)	8 (14.8)
Family characteristics	English main language in the home	144 (75.0%)	144 (79.6%)	94 (76.4)	43 (79.6)	71 (76.3)	124 (79.0)	71 (76.3)	43 (79.6)
	Socio-economic status (SEIFA [‡]) <i>M</i> (<i>SD</i>)	1010.7 (53.6)	1016.1 (55.8)	1003.8 (58.4)	1020.9 (53.14)	1001.4 (61.0)	1016.4 (54.0)	1001.4 (61.0)	1020.9 (53.14)
	Family member with medical conditions:								
	Food allergy	57 (29.7)	59 (32.6)	27 (22.0)	16 (29.6)	18 (19.4)	51 (32.5)	18 (19.4)	16 (29.6)
	Eczema	94 (49.0)	82 (45.3)	55 (44.7)	23 (42.6)	41 (44.1)	70 (44.6)	41 (44.1)	23 (42.6)
	Hay fever [§]	117 (60.9)	121 (66.9)	78 (63.4)	33 (61.1)	59 (63.4)	100 (63.7)	59 (63.4)	33 (61.1)
	Asthma [†]	81 (42.2)	77 (42.5)	55 (44.7)	21 (38.9)	43 (46.2)	65 (41.4)	43 (46.2)	21 (38.9)
Responding parent	Age in years <i>M</i> (<i>SD</i>) [¶]	36.1 (5.7)	36.2 (5.7)	36.1 (5.9)	36.2 (5.7)	36.5 (6.1)	36.2 (5.8)	36.5 (6.1)	35.0 (5.6)
	Mother ^{**}	166 (86.5)	165 (91.2)	105 (85.4)	51 (94.4)	79 (85.0)	142 (91.5)	79 (85.0)	51 (94.4)
	Has cohabiting partner	175 (91.2)	166 (91.7)	116 (94.3)	50 (92.6)	88 (94.6)	145 (92.4)	88 (94.6)	50 (92.6)
	Highest education:								
	Completed University Qualification ^{††}	113 (58.9)	124 (68.5)	70 (56.9)	37 (68.5)	54 (58.1)	108 (68.8)	54 (58.1)	37 (68.5)

* 1 missing value from the ITT IC (all families), 3 missing values from the ITT CC (all families), missing value from ITT IC (seen by 12 months), 1 missing value from PP IC (all families), 1 missing value from the PP CC (all families), 1 missing value from PP IC (seen by 12 months).

† 2 missing values from the ITT CC (all families), 1 missing value from the PP CC (all families).

‡ SEIFA (Socio-Economic Indexes for Areas) was developed by the Australian Bureau of Statistics to rank areas in Australia by relative socio-economic disadvantage, based on the 5-yearly Census data. Mean=1000, SD=100²¹.

§ 1 missing value from the ITT IC (all families), 1 missing value from the ITT IC (seen by 12 months).

¶ 1 missing value from the ITT IC (all families), 2 missing values from the ITT CC (all families), 1 missing value from the ITT IC (seen by 12 months), 1 missing value from the PP IC (all families), 1 missing value from the PP CC (all families).

[†] 3 missing values from the ITT IC (all families), 2 missing values from the ITT CC (all families), 2 missing values from the PP CC (all families).

^{**} 1 missing value from the ITT CC (all families), 1 missing value from PP CC (all families).

^{††} 1 missing value from the ITT IC (all families).

Abbreviations: ITT, intention to treat, PP, per protocol, CC, Control cohort, IC, Intervention cohort

Table 2. Unit costs

Resource	Unit cost (\$)
Initial attendance (<45mins) MBS Item 110*	128.3
Initial attendance (>45mins) MBS Item 132*	224.35
Subsequent attendances (<20mins) MBS Item 116*	64.2
Subsequent attendances (<20mins) MBS Item 133*	112.3
Skin prick test (hospital)	33.15
sIgE test (community)	22.8
sIgE test (hospital)	22.8
Ara h2 test (hospital)	22.8
Oral Food Challenge	1150

* MBS Item unit costs reflect 85% of the full MBS Item benefits

Abbreviations: MBS, Medicare Benefits Schedule, sIgE, serum specific immunoglobulin E.

Table 3. Cost to the Healthcare system for children seen by 12 months

	Intention to treat analysis				Per protocol analysis			
	Intervention Cohort (n=123) 30: allergy clinic visit	Control Cohort (n=54)	Difference (IC – CC)	P value	Intervention Cohort (n=93) of whom 31 referred and seen in allergy clinic	Control Cohort (n=54)	Difference (IC – CC)	P value
Time (mins) spent per patient seen (95% CI)*	73 (69 to 78)	111 (97 to 126)	-38 (-49 to -27)	<0.0001	63 (59 to 66)	111 (97 to 126)	-49 (-63 to -35)	<0.0001
Costs per patient (\$) (95% CI) for:								
SPT (community) SPT (hospital) [†]	1.0 (0 to 3) 13 (11 to 16)	31 (29 to 33)	-16 (-20 to -13)	<0.0001	2 (0 to 3) 9 (6 to 11)	31 (29 to 33)	-21 (-24 to -17)	<0.0001
sIgE test (community) sIgE test (hospital)	14 (13 to 16) 1.0 (0.3 to 1.8)	1.3 (0.0 to 3)	14 (12 to 16)	<0.0001	18 (16 to 20) 1.0 (0.2 to 2.1)	1.3 (0.0 to 3.0)	18 (15 to 20)	<0.0001
ARA h2	0 (0 to 1)	0 (0 to 1)	0 (-1 to 1)	0.85	0 (0 to 0)	0 (0 to 1)	0 (-1 to 0)	0.19
Oral Food Challenge	78 (25 to 150)	106 (22 to 217)	-28 (-135 to 77)	0.62	11 (0 to 32)	106 (22 to 217)	-95 (-217 to 0)	0.08
MBS Item fees (comm.) [‡] MBS Item fees [§] (hospital)	184 (174 to 195) 66.9 (55.3 to 78.6)	179.8 (167 to 193.5)	5 (-7 to 17)	0.47	236 (222 to 250) 41.7 (27.6 to 55.5)	179.8 (167 to 193.5)	56 (42 to 70)	<0.0001
Average costs (\$) per/patient seen (95% CI)	333 (270 to 414)	319 (225 to 430)	14 (-97 to 118)	0.81	284 (250 to 324)	319 (225 to 430)	-35 (-156 to 62)	0.54

Total costs (\$) in 12 months (95% CI)	45,973 (37,238 to 57,167)	17,213 (12,168 to 23,216)	28,759 (19,805 to 39,400)	<0.0001	30,661 (26,996 to 34,970)	17,213 (12,168 to 23,216)	13, 448 (6,141 to 19,980)	<0.001
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* assuming patients referred to the RCH by a community paediatrician had an average contact of 111 minutes (as observed for other patients attending the RCH).

† 1missing value from the ITT CC, 1 missing value from the PP CC.

‡ 5 missing values from the ITT IC, 5 missing values from the PP IC.

§ 1 missing value from the ITT CC, 1 missing value from the ITT IC, 1 missing value from the PP IC, 1 missing value from the PP CC.

Abbreviations: ITT, intention to treat, PP, per protocol, CC, Control cohort, IC, Intervention cohort

Table 4. Out of pocket costs to the family within 12 months

	Intention to treat analysis				Per protocol analysis			
	Intervention Cohort (n=163)	Control Cohort (n=135)	Difference (IC – CC)	p value	Intervention Cohort (n=82)	Control Cohort (n=121)	Difference (IC – CC)	P value
Average (mean) costs per patient (\$) at 12 months (95% CI) for:								
Study visits								
Paediatrician Visits OOP	49.2 (34.2 to 64.3)	0	49.2 (32.8 to 65.7)	<0.0001	86.7 (60.1 to 113.3)	0	86.7 (65 to 108.3)	<0.0001
Community Blood tests OOP	2 (0.3 to 3.6)	0	2 (0.2 to 3.8)	0.03	4 (0.7 to 7.2)	0	4 (1.3 to 6.6)	0.004
Total visits OOP (visit and blood tests OOPs)	51.2 (35.9 to 66.6)	0	51.2 (34.4 to 68.1)	<0.0001	90.7 (63.5 to 117.7)	0	90.7 (68.6 to 112.7)	<0.0001
Travel to visit & blood tests OOP*	21.3 (17.1 to 25.5)	7.4 (4.6 to 10.3)	13.9 (8.6 to 19.2)	<0.0001	31.1 (24.3 to 38)	8.3 (5.1 to 11.5)	22.8 (16 to 29.6)	<0.0001
Total visit OOP[†]	72.5 (56.1 to 89)	7.4 (4.6 to 10.3)	65.1 (46.9 to 83.3)	<0.0001	121.8 (94.1 to 149.4)	8.3 (5.1 to 11.5)	113.4 (90.6 to 1336.3)	<0.0001
Other services accessed								
GP OOP [‡]	1.8 (0.4 to 3.1)	3 (1 to 5)	-1.2 (-3.6 to 1.1)	0.30	0.4 (0 to 1.2)	3 (0.9 to 5.2)	-2.6 (-5.3 to 0)	0.05
Paediatrician OOP	5.8 (0.8 to 10.7)	6.3 (0.4 to 13)	-0.5 (-8.7 to 7.6)	0.90	5.2 (0 to 11.8)	6.2 (0 to 13.6)	-1 (-11.4 to 9.4)	0.85
OTC OOP	23.4 (19 to 27.8)	16.5 (12.9 to 20.2)	6.9 (1.0 to 12.7)	0.02	24.8 (18.6 to 31)	15.6 (12 to 19.3)	9.2 (2.5 to 15.9)	0.01
Other services accessed OOP [§]	25.9 (10.7 to 41)	55.8 (31.3 to 80.3)	-29.9 (-2.2 to -57.6)	0.03	18.5 (0.6 to 36.5)	39.5 (17.9 to 61.1)	-21 (-51 to 9)	0.17
Total OOP of all other services accessed	56.8 (38 to 75.6)	81.6 (54.9 to 108.3)	-24.8 (-56.6 to 7)	0.49	49 (29.5 to 68.4)	64.4 (41.2 to 87.7)	-15.4 (-47.7 to 16.9)	0.35
TOTAL OOP[¶]	129.4	89.1	40.3	0.03	170.7	72.7	98	<0.0001

	(104.3 to 154.5)	(62.5 to 115.7)	(3.8 to 76.8)		(135.9 to 205.6)	(49.5 to 95.9)	(58.1 to 138)	
Parents "days off" to attend visits**	152.9 (116.4 to 189.4)	70.8 (40.7 to 100.9)	82.1 (33.7 to 130.4)	0.001	209.6 (152.4 to 266.8)	79 (45.7 to 112.3)	130.6 (69 to 192.2)	<0.0001
Parents "days off" to attend other services	236.1 (132.3 to 334)	268.4 (156.8 to 380)	-32.3 (-184.4 to 120)	0.68	169.8 (73.8 to 264.7)	225.1 (136.1 to 314.1)	-55.3 (-188.5 to 77.8)	0.41
Total productivity losses	389 (273.8 to 504.2)	339.2 (222.2 to 456.3)	49.8 (-115 to 214.6)	0.55	379.4 (250.5 to 508.3)	304.1 (205.7 to 402.6)	75.3 (-83.6 to 234.1)	0.35

* 2 missing values from the ITT IC, 1 missing value from the PP CC.

† 3 missing values from the PP CC.

‡ 1 missing value missing value from the ITT IC, 5 missing values from the PP CC.

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‡ 2 missing values from the PP CC.

† 3 missing values missing value from the ITT IC, 8 missing values from the PP CC.

** 2 missing values from the PP CC.

Abbreviations: OOP, out of pocket; OTC, over the counter, ITT, intention to treat, PP, per protocol, CC, Control cohort, IC, Intervention cohort

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Title:

Costs and uptake of a community model of paediatric food allergy care versus specialist hospital care: A before-and-after controlled trial

Date:

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