

ASSOCIATION BETWEEN HOUSEHOLD LIVING CONDITIONS AND ECZEMA IN ADOLESCENTS LIVING IN LIMPOPO PROVINCE, SOUTH AFRICA

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ABSTRACT

Background: This is the third study that has applied the International Study of Asthma and Allergies in Childhood (ISAAC) methodology in southern Africa and is the first to be carried out in Limpopo Province, South Africa.

Objective: To assess the 12-month prevalence of eczema symptoms (ES) and the prevalence of ever having had eczema (EE) along with potential risk factors.

Setting: Within a 60 km radius from the Polokwane city centre, Limpopo Province.

Methods: The survey was conducted during August 2004 and February 2005. Children (13-14 years) completed the questionnaires in English, Afrikaans or North Sotho ($N = 3\,926$).

Results: The 12-month prevalence of ES (9.6%) was lower than the prevalence rate of EE (19.4%). The multivariate logistic regression model revealed that being male, English-speaking, living in a rural area, living more than a 15-minute walk or a 5-minute drive from a clinic or being exposed to environmental tobacco smoke at home was significantly associated with ES. Being male, having running water in the household and using coal and/or paraffin with gas and/or electricity during cooking were significantly associated with EE.

Conclusion: Eczema appears to be a substantial public health problem in the Polokwane area. Hopefully, detailed analytical intervention studies will scrutinise these results in the near future.

mation of the skin should be 'dermatitis'. The term 'eczema' describes an aggregation of several skin diseases with clinical characteristics in common, involving a genetically determined skin barrier defect. The WAO stipulates that the term 'atopy' cannot be used until an IgE sensitisation has been documented by IgE antibodies in serum or by a positive skin-prick test.

There is a paucity of data on the prevalence of eczema in South Africa. Two earlier studies that were conducted during February to August 1995 and March to September 2002 reported on the prevalence of eczema among teenagers living in Cape Town.^{9,10} Both studies applied the International Study on Asthma and Allergies in Childhood (ISAAC) methodology. ISAAC was instituted in 1992 to maximise the value of epidemiological research into asthma and allergic disease by establishing a standardised methodology and facilitating international collaboration.⁴

Epidemiological studies on twins suggest that genetic factors play a role in the disease.¹¹ Some studies also reported on the association between environmental factors and the increase of eczema prevalence rates.¹²⁻¹⁴ The role of socio-economic factors is not yet fully clear.^{1,9,15,16} Genetic factors may also interact with environmental and socio-economic factors. Investigating risk factors for eczema is also further complicated by the fact that associations have been reported between the disease and upper and lower respiratory tract infections.¹⁷⁻¹⁹

This study had a cross-sectional design and applied the ISAAC Phase III methodology. It is the third study that has applied the ISAAC methodology in southern Africa and the very first of its kind to be carried out in the northern part of South Africa. The aims of this study were: (i) to compile information on the prevalence and potential risk factors of eczema symptoms (hereafter ES) and ever having had eczema (hereafter EE) for 13-14-year-old children in the Polokwane area; (ii) to compare results with other regions where ISAAC studies have been conducted; and (iii) to contribute to the current body of knowledge regarding the prevalence and potential risk factors of eczema among adolescents, specifically in the context of a developing country.

INTRODUCTION

Worldwide the risk of developing eczema is reported to be increasing among children and adolescents and currently affects approximately 5-20%.¹⁻⁴ Eczema is not life-threatening, but the constant scratching associated with eczema may result in skin damage, secondary infection and sleep loss.⁵⁻⁷

In October 2003 the Nomenclature Review Committee of the World Allergy Organisation (WAO) published an update of the European Academy of Allergology and Clinical Immunology (EAACI) document, which describes the terminology for skin allergies.⁸ The WAO recommends that the umbrella term for local inflam-

METHODS

Study area

This study was part of a bigger project that investigated the baseline prevalence rates of allergic diseases among children living in the vicinity of a platinum smelter, located 60 km from the city centre of Polokwane, the capital of Limpopo Province. The study was thus conducted within a 60 km radius from the Polokwane city centre. The population of the Polokwane municipality was 483 000 in 2001, of whom the majority (73%) lived in rural areas on the periphery of the municipality.²⁰ A poverty report confirmed that Limpopo Province is the second poorest province in South Africa.²⁰ Polokwane is developing at a rapid pace and the mining industry has boomed over the last decade. Rural marginalised areas, like most of Limpopo Province, are faced with environmental concerns and

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risks, typical of those experienced by industrialised cities and many developing countries.

Study participants and period

Adolescents (13-14 years old) participated in the study during August 2004 (winter), October 2004 (spring) and February 2005 (summer).

Questionnaire survey

A questionnaire was prepared following the ISAAC format for the core questions aimed at the assessment of the prevalence of eczema and its symptoms.⁴ Questions assessing potential risk factors were included, namely those addressing indoor air pollution from the combustion of coal or paraffin for cooking. The questionnaire was translated into North Sotho, which is the primary local language spoken by the communities in the study area. A different translator translated it back to English in order to ensure consistency with the original. The questionnaire was also made available in English and Afrikaans, which are the two other languages spoken in the area. The Afrikaans version was already available as it had been used in the Cape Town ISAAC study.⁹

A list of 163 secondary and combined schools was provided by the Limpopo Province Department of Education. Eighty-five secondary and combined schools were randomly selected from this list and eventually 76 secondary and combined schools participated in the study. Schools were contacted by telephone or fax to obtain permission for visits. Where necessary, at least three attempts were made to obtain such permission. Children in all grade 7 and 8 classes from the 76 schools were requested to complete the questionnaires in English, Afrikaans or North Sotho at the school. Children in grades 7 and 8 are usually 13-14 years old – the target population of this study.

Twelve field workers were selected and attended a one-day training session on how to undertake the study. One of the researchers accompanied each of the six fieldwork teams on at least one day to ensure adherence to the protocol.

Data capture process

Data were entered into an EPIDATA file and validated by blind double entry.

Health outcomes and potential risk factors

In accordance with the ISAAC methodology, participants were considered to have had ES in the previous 12 months when they answered in the affirmative to all three of the following questions:

1. Did you ever have an itchy rash that was coming and going for at least 6 months?
2. Did you have this itchy rash at any time in the last 12 months?
3. Has this itchy rash at any time affected any of the following places: the folds of the elbows, behind the knees, in front of the ankles, under the buttocks, or around the neck, ears, or eyes?

To explore the effects of disease classification in relation to these symptoms, participants were also asked whether they had ever had eczema (EE).

Risk factors assessed included household conditions, demographics and health-seeking behaviour (Table I). The ISAAC protocol stipulates that separate analyses should be conducted for different ethnic groups.^{21,22}

Ethnicity was not assessed directly in the questionnaire. Language was used as a proxy to indicate race; in this case, North Sotho was used as a proxy to indicate black/African ethnicity. English and Afrikaans are mostly the mother tongue of the other three race groups. Under apartheid, South Africans were categorised into one of four socially defined race or ethnic groups: White (mainly European ancestry), Asian (Indian sub-continent ancestry), African or black (descent primarily from one of a number of Bantu language groups in southern Africa) and Coloured (general grouping, including a mixture of Black, Malay, European and indigenous Khoisan ancestry). Race is currently still linked to socio-economic status and educational status.

Statistical analysis

The data were extracted from EPIDATA and statistically analysed with the statistical package STATA V9. Prevalence rates for the health outcomes and proportion of risk factors under investigation were calculated by dividing the number of participants who responded in the affirmative to a particular question by the number of questionnaires completed. This resulted in each question having a slightly different sample size.

Crude and adjusted odds ratios (OR) and 95% confidence intervals (CI) were calculated to estimate the likelihood of having ES or having had EE given the presence of a potential risk factor, using univariate and multivariate logistic regression analyses (LRA). Not all children who were in grades 7 and 8 were 13-14 years old. The data analysis was restricted to 13-14 year olds. Observations to all questions marked as 'do not know', 'not stated' or 'other response' were set as missing. All missing values were excluded from the LRA.

Ethical approval

Approval was granted by the University of Pretoria Ethics Committee and the Ministry of Education, Limpopo Province. Consent was given by the parents or guardians of the participants. The data collectors were instructed to keep all information confidential. Anonymity was maintained and the names of the participants were not recorded.

RESULTS

The prevalence rate of ES experienced within 12 months prior to the study was 9.6%, while that of EE was 19.4%. Of the 733 participants who had EE, 220 (30.0%) indicated that they had had ES during the 12 months prior to the study. The majority (95.8%) who reported never having had EE ($N = 2\,742$) reported not having had ES in the 12 months that preceded the study ($N = 2\,627$); 4.2% of the children who had ES in the past 12 months had never been told that they had eczema.

Table I lists the characteristics of study participants. Table II indicates that for the univariate LRA, the following potential risk factors significantly increased the likelihood of ES by 334%, 27% and 36%, respectively: belonging to the English speaking group; living one hour's walk or 15 minutes drive from the nearest clinic/hospital; or being exposed to environmental tobacco smoke (ETS) at home. Two potential factors were protective: being male and living in a rural area. All of these five potential risk and protective factors remained significantly associated with ES in the multivariate LRA. The adjusted OR of four of these five potential risk and protective factors were similar to the crude ones. The OR of belonging to the English-speaking group increased from 4.34 to 5.18 in the adjusted analysis.

Table I. Characteristics of study participants (13-14 years) (N = 3 926)

Characteristic	No.	Percentage (%)
Sex of child		
Male	1 641	41.8
Female	2 278	58.0
Not stated	7	0.18
Language		
Afrikaans	384	9.8
English	1 163	29.6
North Sotho	2 379	60.6
Type of area*		
Urban	1 920	48.9
Rural	2 006	51.1
Time period lived in current suburb/village		
< 3 years	849	21.6
≥ 3 years	2 938	74.8
Other response	139	3.5
Travel time to nearest clinic or hospital from home		
15-min walk or 5-min drive	1 891	48.2
1-hour walk or 15-min drive	1 295	33.0
> 1-hour walk or > 30-min drive	601	15.3
Other response	139	3.5
Type of house [†]		
Informal	701	17.9
Formal	3 225	82.1
Cooking fuel type [‡]		
Combination of dirty and clean	1 954	49.8
Clean	1 972	50.2
Having running water in house		
Yes	1 644	41.9
No	2 187	55.7
Other response	95	2.4
ETS exposure at home		
Yes	935	23.8
No	2 875	73.2
Other response	116	3.0
Having pets or animals in and around house		
Yes	2 241	57.1
No	1 622	41.3
Other response	63	1.6
Ever had recurrent itchy rash		
Yes	715	18.2
No	2 983	76.0
Other response	228	5.8
Itchy rash in previous 12 months		
Yes	636	16.2
No	1 684	42.9
Other response	1 606	40.9
Ever had this rash in flexures		
Yes	679	17.3
No	1 230	31.3
Other response	2 017	51.4
Eczema symptoms in previous 12 months		
Yes	377	9.6
No	3 361	85.6
Other response	188	4.8
Ever had eczema		
Yes	761	19.4
No	2 807	71.5
Other response	358	9.1

*Urban = living in Polokwane or Seshego; rural = living in Mankweng, Mogodumo, Bahlaloga, Maraba or Maune

[†]Formal = brick; informal = corrugated iron, mud, or combination with or without bricks

[‡]Clean = gas and/or electricity; combination of clean and polluted = coal, paraffin, gas and/or electricity

Characteristic	No.*	Eczema symptoms in previous 12 months		OR	95% CI	Adjusted OR	95% CI
		No (%) [†]	Yes (%) [†]				
Sex of child							
Female	2 177	88.3	11.7	1		1	
Male	1 555	92.2	7.8	0.64	0.51-0.80	0.64	0.51-0.82
Language							
Afrikaans	372	94.9	5.1	1		1	
English	1 124	81.0	19.0	4.34	2.67-7.06	5.18	3.15-8.50
North Sotho	2 242	93.5	6.5	1.28	0.79-2.10	2.40	1.40-4.09
Type of area							
Urban	1 842	85.8	14.2	1		1	
Rural	1 896	93.9	6.1	0.39	0.31-0.49	0.49	0.37-0.66
Time period lived in current suburb/village							
< 3 years	796	89.9	10.1	1		-	-
≥ 3 years	2 826	89.7	10.3	1.02	0.79-1.33	-	-
Travel time to nearest clinic or hospital from home							
15-min walk or 5-min drive	1 812	90.2	9.8	1		1	
1-hour walk or 15-min drive	1 232	87.9	12.1	1.27	1.01-1.60	1.35	1.07-1.72
> 1-hour walk or > 30-min drive	577	92.4	7.6	0.76	0.54-1.08	0.97	0.68-1.40
Type of house							
Informal	652	88.3	11.7	1		-	-
Formal	3 086	90.2	9.8	0.82	0.63-1.07	-	-
Cooking fuel type							
Clean	1 872	90.5	9.5	1		-	-
Combination of dirty and clean	1 866	89.3	10.7	1.14	0.92-1.41	-	-
Having running water in house							
No	2 083	89.6	10.4	1		-	-
Yes	1 586	90.1	9.9	0.95	0.76-1.18	-	-
ETS exposure at home							
No	2 758	90.5	9.5	1		1	
Yes	893	87.6	12.4	1.36	1.07-1.72	1.44	1.12-1.85
Having pets or animals in and around house							
No	2 139	89.9	10.1	1		-	-
Yes	1 557	89.9	10.1	1.01	0.81-1.25	-	-

*Totals for each characteristic are different due to difference in missing values. [†]Percentage of No.

Characteristic	No.*	Eczema symptoms in previous 12 months		OR	95% CI	Adjusted OR	95% CI
		No (%) [†]	Yes (%) [†]				
Sex of child							
Female	2 093	76.4	23.6	1		1	
Male	1 471	81.8	18.2	0.72	0.61-0.85	0.73	0.61-0.86
Language							
Afrikaans	361	81.7	18.3	1		-	-
English	1 041	77.9	22.1	1.27	0.93-1.72	-	-
North Sotho	2 166	78.5	21.5	1.22	0.92-1.63	-	-
Type of area							
Urban	1 722	79.5	20.5	1		-	-
Rural	1 846	77.9	22.1	1.10	0.94-1.29	-	-
Time period lived in current suburb/village							
< 3 years	744	77.7	22.3	1		-	-
≤ 3 years	2 717	78.7	21.3	0.94	0.77-1.14	-	-
Travel time to nearest clinic or hospital from home							
15-min walk or 5-min drive	1 718	79.2	20.8	1		-	-
1-hour walk or 15-min drive	1 174	78.2	21.8	1.06	0.88-1.27	-	-
> 1-hour walk or > 30-min drive	566	78.3	21.7	1.05	0.84-1.33	-	-
Type of house							
Informal	635	75.1	24.9	1		1	
Formal	2 933	79.4	20.6	0.78	0.64-0.96	0.88	0.71-1.08
Cooking fuel type							
Clean	1 773	81.9	18.1	1		1	
Combination of dirty and clean	1 795	75.5	24.5	1.47	1.25-1.73	1.27	1.05-1.53
Having running water in house							
No	2 021	75.9	24.1	1		1	
Yes	1 480	82.6	17.4	0.67	0.56-0.79	0.75	0.62-0.91
ETS exposure at home							
No	2 638	78.7	21.3	1		-	-
Yes	843	79.0	21.0	0.98	0.81-1.19	-	-
Having pets or animals in and around house							
No	2 062	78.3	21.7	1		-	-
Yes	1 467	79.3	20.7	0.94	0.80-1.11	-	-

*Totals for each characteristic are different due to difference in missing values. [†]Percentage of No.

The univariate LRA results listed in Table III indicate that a slightly different mix of potential risk factors significantly increased the likelihood of EE. Participants who lived in households that used a combination of fuels for cooking were 47% more likely to have EE. Three potential factors were protective by decreasing the likelihood of EE: being male (by 28%); living in a formal house (by 22%); or having running water in the house (by 33%). Including these four significant potential risk and protective factors in the multivariate LRA revealed that type of cooking fuel used, sex of the participant and having running water in the house remained significantly associated with EE. The adjusted OR of the latter two potential protective factors were similar to the crude ones. The association between EE and cooking fuel type decreased from 1.47 to 1.27 in the adjusted analysis.

DISCUSSION

The results from this study indicate that the prevalence rates of ES and EE were high: 9.6% and 19.4% respectively.

Williams *et al.*¹ published the first global comparison of the prevalence of ES and EE based on the ISAAC Phase I studies. These studies were conducted between 1992 and 1995 in 56 countries among 715 033 children (6-7 and 13-14-year-olds). The design of Phase III studies is similar to those of Phase I. The same sampling frame, method of selecting schools and method of selecting children within schools are used during both phases.^{4,21} Prior to the 2003 WAO recommendations, eczema was referred to as 'atopic eczema' in all ISAAC studies. The term is now referred to as 'eczema', as recommended by the WAO.⁸

The lowest and highest 12-month prevalence of ES was 0.6% in Pune, India and 20.5% in Kottayam, India.¹ The lowest prevalence of EE was 0.3%, in Chandigarh in India, and the highest was 49.3%, in Uppsala/Stockholm in Sweden. The ISAAC study that was conducted in Cape Town reported a 8.3% 12-month prevalence rate for ES and a 9.6% prevalence rate for EE.⁹ The follow-up ISAAC study in Cape Town reported the prevalence rate of a flexural rash at any time as 21.6%.¹⁰ ISAAC studies were conducted in other African countries, namely Algeria, Ethiopia, Kenya and Nigeria.¹ Among the African countries, the lowest 12-month prevalence of ES was 3.2% in Jimma, Ethiopia and the highest was 19.9% in Addis Ababa, Ethiopia. The lowest prevalence of EE was 5.6% in Jimma, Ethiopia and the highest was 38.4% in Ibadan, Nigeria.¹ It would be useful to know which household living characteristics are significantly associated with ES and EE in these four African ISAAC studies in order to compare their results with ours.

In this study female participants had significantly higher ES and EE prevalence rates. Mercer *et al.*⁹ also observed that males were less at risk of having ES (OR = 0.59, 95% CI: 0.47-0.74) or EE (OR = 0.68, 95% CI: 0.55-0.83). These findings support the influence of genetic factors on eczema to some extent. Another explanation might be that girls tend to spend more time at home in close contact with the identified potential risk factors – polluting fuels and ETS.

All the risk and protective factors that remained significantly associated with ES or EE (except the sex of the participants, travel time to clinics and ETS) might be surrogate markers for socio-economic status. Studies have found that a lower socio-economic status increases the risk for developing eczema.^{1,9,15,16} Mercer *et al.*⁹ also report that eczema prevalence rates were higher in urban than rural areas.

A review that focused on studies conducted in Europe indicated that traffic-related air pollution increased the risk of developing eczema.¹² Other epidemiological studies reported on the association between current ETS exposure and ETS exposure during pregnancy and lactation with ES.^{23,24} Traffic, ETS and the combustion of polluting fuels emit numerous air pollutants, of which NO₂ and carbon particles are examples. Studies reported that NO₂ and carbon particles interact or bind to allergen particles and thereby increase their allergenicity.²⁵⁻³¹

European studies report mixed results on whether pet ownership increases the likelihood of having eczema.³² Pets or animals did not have a detrimental impact on the health outcomes in this study. It may be that the risk of indoor air pollution, ETS exposure and lack of clean water overwhelms the risk posed by pet allergens in developing countries and, therefore, needs further investigating.

Strengths of the study were that: (i) it adhered to the validated ISAAC methodology; (ii) postgraduate public health students from the community were recruited for the fieldwork; and (iii) the recommended sample size of 3 000 was met, as stipulated in the ISAAC protocol.⁴

There are some important limitations to this study, which should be taken into account in the interpretation of the results. First, the study had a cross-sectional design, like all the other ISAAC studies. Cross-sectional studies are weak to prove causation as they are subject to difficulties in the interpretation of the temporal sequence of events, since health status and determinants are measured simultaneously. However, our findings are supported by other studies, as discussed previously.

Second, the generalisation of the results is influenced by the non-response rate. The response rate was difficult to estimate as no record was kept of the number of questionnaires distributed in relation to the number of questionnaires completed and returned. As most of the schools do not have an official or unofficial class list, it was also not possible to retrospectively estimate the response rate on the basis of the number of forms returned. A representative of the ISAAC committee informed the authors that not having an accurate response rate does not automatically rule out the inclusion of the Polokwane data from the ISAAC database as the committee also considers other data qualities. The questionnaires were distributed to all the children at a particular education level (grades 7 and 8) instead of all children that belong to the specific age group. However, it is most likely that the majority of 13-14 year olds were in grades 7 and 8, and not in other grades. This study focused only on those children who attended school and participated in the survey on the day the field workers visited the school. It was not possible to trace those children who were absent. One of the co-authors who conducted the fieldwork assured the other co-authors that most of the children were present at the time of the fieldwork, which coincided with school test periods. We are confident that the school attendance was high during the study. Thus the bias that might be introduced by non-response is assumed to be relatively low for this study.

Third, reliance on self-reported data includes a risk of misclassification of disease and exposure status resulting in statistical significance arising by chance. No clinical measurements were undertaken. Mercer *et al.*⁹ have found that there is no word for 'eczema' in Xhosa; however a North Sotho word exists. Exposure to potential chemical risk factors (ETS and indoor air pollution) was ascertained from binary-coded questions (yes/no). Some misclassification of symptoms attribut-

able to other diseases and conditions (e.g. scabies) that may be prevalent in this population is unavoidable, but because these other diseases and conditions are not likely to be dependent on the household characteristics studied here, the result of such non-differential misclassification is expected to be an underestimation of the extent of true effects on ES. It is also likely that perceptions of questions related to ES symptoms may differ between rural South African participants and their counterparts from developed countries. Therefore, even if the translation of ES and the disease itself may be perfect, people living in unhygienic conditions may be less likely to answer positively to such questions.

Fourth, differential and/or non-differential misclassification may have influenced the risk estimates. Many households in South Africa in general use a combination of cooking and heating fuels. The calculated effects may be underestimated if only the exclusive use of polluting fuels (coal/paraffin) is considered and not the use of these fuels in combination with gas and/or electricity. However, none of the households under investigation used coal exclusively or paraffin exclusively. No quantitative exposure assessment (including duration of exposure, as reflected by frequency and duration of fuel use for heating and cooking per day) was conducted during the investigation. It is recommended that future studies include a question on the type of fuels used for heating as well. Exposure to smoke from polluting fuels during heating is much longer than exposure during cooking. Notwithstanding the lack in terms of quantitative measurement of air pollution exposure levels and clinical measurements for eczema, the relative uniformity in the significance of crude and adjusted effects implies a probable exposure-response relationship between the type of fuel used for cooking and EE. This exposure-response was also observed between ETS exposure and ES.

Fifth, other factors not recorded in this study that may contribute to ES and EE included: outdoor and indoor air pollution sources (e.g. location of household close to industry, transportation sources or waste fill sites, insecticide or fertiliser use, allergens such as pollen, dust, fungal spores from mildew and moulds) along with meteorological variables (precipitation, temperature, humidity), child's birth weight, length of breastfeeding as well as the likelihood of HIV infection within the sample, given South Africa's high HIV prevalence. Excluding these risk factors from the analysis might introduce substantial bias (differential or non-differential). Thus the direction of bias on the calculated association measures is not easy to predict. As the association between these excluded risk factors and those investigated in this study is not available from the literature, it is impossible to predict the direction of the potential bias on the association measure.

In order to improve health for the South African population though epidemiological studies it is imperative that future studies attempt to minimise systematic and random errors and, consequently, strengthen their validity and accuracy. It is hoped that future analytic studies will validate and improve the understanding of how these identified potential risk and protective factors increase and decrease the risk of eczema development among children. Such research is important as 41% and 48% of 11 million South African households still used polluting fuels (such as wood, animal dung, crop residues, coal or paraffin exclusively or in combination) for cooking and heating, respectively during 2001, even when access to electricity was available.³³ The 2001 South African Census also revealed that the majority (70%) of the households used electricity for lighting during 2001 and that nearly a third of the 11 million households belong to the informal category.³³

The 1998 South African Demographic and Health Survey report (SADHS) highlighted that 42% of men (>15 years) and 11% of women (>15 years) smoked tobacco products.³⁴ Only 40% of households had piped water in their homes during the 1998 SADHS survey, while 43% of people had to get their water from public taps around their houses and 16% from rivers or dams.

However, given the fact that only 5% of the national research budget is spent on health-related research in South Africa, compared to 30% in developed countries, it is important that analytical studies do not merely document the impact of known risk factors.³⁵ Instead, such studies should provide a basis for designing technical or sociobehavioural interventions to minimise exposure to ETS and indoor pollution from the combustion of polluting fuels used in cooking or heating. The results from such studies will hopefully be scrutinised in more detailed intervention studies, which may inform and influence policy decisions and form a basis for a health promotion intervention in the community.

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Declaration of conflict of interest

The authors declare no conflict of interest.

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