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Momordica charantia L. for hyperlipidaemia: A randomised controlled assessment of the Ghanaian herbal medicinal product *MCP-1*

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ABSTRACT

Cardiovascular diseases are a public health burden for developing countries like Ghana. Scientifically validated herbal medicines are viable options in the prevention and treatment of such conditions. In this study, a randomised controlled trial involving 15 healthy subjects identified with hyperlipidaemia was undertaken. Treatment comprised a traditional Ghanaian herbal formulation prepared from the leaves and twines of *Momordica charantia* (*MCP-1*) with a standard dietary guideline. A control group was managed using a standard dietary guideline alone. In all, 15 subjects completed the study: *MCP-1* had 10 subjects and 5 subjects in the control group. At the termination of the trial after 8 weeks, reduction in lipoprotein values were recorded for all participants. In the *MCP-1* group, triglycerides reduced by 3.46 % compared to 3.37 % for the control while total cholesterol was also reduced by 9.78 % and 9.43 % in the *MCP-1* and control groups respectively. High density lipoproteins (HDL) levels increased by 6.92 % for *MCP-1* and 3.92 % for the control group. However, these changes were not statistically significant except in the instance of the low-density lipoproteins (LDL-c; CI: -41.24 to -19.76) and very low-density lipoproteins (VLDL-c; CI: -26.87 to -8.192). Changes to other disease indices such as blood pressure (BP), fasting blood sugar (FBS) and body mass index (BMI) were also not different between the 2 groups. *MCP-1* was well tolerated among the subjects and was shown to be safe from the biochemical and haematological indicators. The product, *MCP-1* has therefore been shown to be a safe and prospective anti-lipidaemic agent.

1. Introduction

Cardiovascular diseases (CVD) present a public health challenge for developing countries. Incidence per capita has been increasing for the past three (3) decades. Between 1990 and 2013, the sub-Saharan African region remained the only part of the world where CVD-related deaths increased. This situation is in contrast to other parts of the world where mortality has been declining steadily (Agyemang et al., 2012; Roth et al., 2015). The most important modifiable risk factor for prevention of cardiovascular diseases is serum lipid level (Pan et al., 2016; Sun et al., 2014). This role of lipoproteins in cardiovascular disease outcomes is well established.

Cholesterol-rich lipoproteins (CRL) are reported to interrupt and alter vascular function. They affect vascular structure through accumulation in the lining of the vascular wall and interfere with endothelial function causing plaques, lesions, occlusion, and emboli. These lipoproteins are also responsible for delayed recovery, healing and challenges with the management of ischaemia/reperfusion injury (D'Agostino et al., 2008; Nordestgaard et al., 2010; Wing et al., 2010). Ultimately, CRLs impair microcirculation with a reduction in bioavailability of vascular nitric oxide, elevated oxidant stress and the creation of a strongly proinflammatory state which results in profound

Abbreviations: BMI, body mass index; CRL, cholesterol rich lipoproteins; FBS, fasting blood sugar; HDL-c, high density lipoprotein cholesterol; *MCP-1*, *Momordica charantia* powder; LDL-c, low density lipoprotein cholesterol; TCHOL, total cholesterol; VLDL-c, very low-density lipoprotein cholesterol.

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impairment to vascular reactivity (Stajic and Djonovic, 2017).

The chronic nature of hyperlipidaemia affects the treatment-seeking attitude of patients. The choice of botanicals by patients is thus very common because of the side effects and cost associated with the standard treatments. *Momordica charantia* L., a vine of the family Cucurbitaceae, is a plant that is noted for its lipid lowering and anti-diabetic effects. This plant is widely distributed in tropical and subtropical regions of the world. It is known by the common names: Bitter melon, Bitter gourd and African cucumber. In the Ghana, *M. charantia* is referred to as "Nyanya" or "Nyenye" in the local *Fante* language of Ghana (Basch et al., 2003; Mshana et al., 2001; Reyes et al., 2006). In Ghanaian traditional medicine, a decoction of the leaves or whole plant is used to treat dysmenorrhoea, toothache, diarrhoea, snake bite, furuncle, diabetes, cancers and hypertension. The lipid lowering effect of various formulations of *M. charantia* have also been extensively reviewed and reported (Grover et al., 2002; Harinantenaina et al., 2006; Jia et al., 2017).

MCP-1 is a Ghanaian herbal product from the leaves and vines of *Momordica charantia* that has served as a traditional preparation for the management of infections, and as an adaptogen. This 30-year-old product has over the past decade been adopted by clinicians at the Centre for Plant Medicine Research, Mampong-Akuapem, for the management of diabetes mellitus and cases of hyperlipidaemia with some success. In this randomised controlled study, the authors sought to establish if there is better control of lipidaemia in patients who receive *MCP-1* together with a standard dietary regimen compared to those managed with the dietary regimen alone. The clinical safety of the product was also investigated. This is the first step towards justifying the off-label use of the product as an anti-lipidaemic agent and to conduct a larger clinical trial.

2. Methods

2.1. Ethical considerations

The protocol used for the study, the consent form and the patient information sheet were reviewed and approved by the supervisory research committee of the Centre for Plant Medicine Research prior to the initiation of the study (CPM/A.127/2/2015). The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice (World Medical Association, 2013). Written informed consent was obtained from every study subject prior to the trial-related activities. The consent forms were retained by the investigator. The general guidance provided for human studies were also given to participants. These included, but were not limited to, the freedom to withdraw at any stage of the study, protection of their private data and their right to standard care if they opt out of the study.

2.2. Study site

The trial was conducted at the clinic of the Centre for Plant Medicine Research, Mampong-Akuapem, Ghana. This research institution hosts an out-patient clinic and has the mandate to undertake research on traditional herbal remedies used in Ghana. The clinic has an average attendance of about 70 patients a day with herbal medicines being offered as the first line treatment for most conditions.

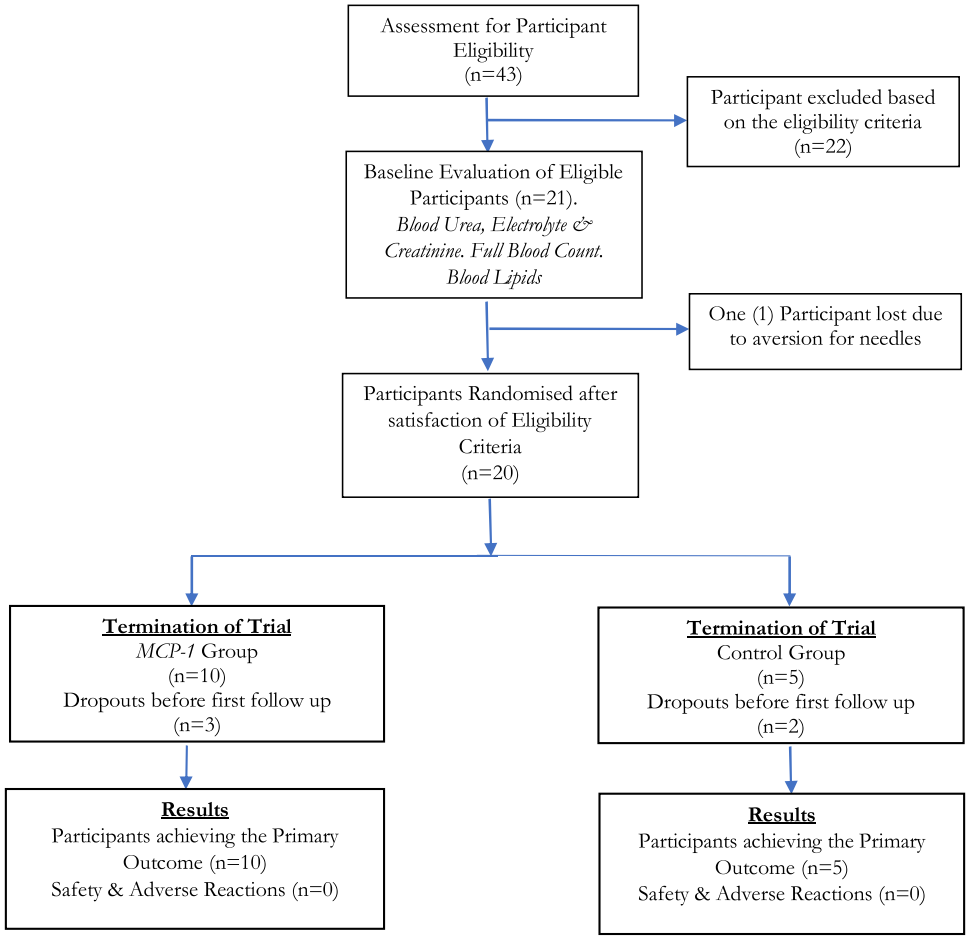

Fig. 1. Flow chart of the trial procedures and results obtained from the study.

2.3. Study design

A prospective, non-blinded, randomised controlled study exploring the potential clinical benefits of employing the herbal medicinal product *MCP-1* as an anti-lipidaemic agent was undertaken. The treatment group received *MCP-1* and a standard dietary regimen while the comparator group were assigned the dietary regimen alone. Protocol for the trial is illustrated as Fig. 1.

2.4. Randomisation and subject allocation

A blocked randomisation was used in assigning subjects to either the treatment or control group. Assignment was done at a ratio of 2:1 i.e. *MCP-1* and the dietary control respectively. To achieve randomisation participants were asked to pick without replacing from a box that contained 9 folded papers with 6 labelled for the herbal treatment and 3 for the dietary control. At the end of each round of recruitment and randomisation, the herbal treatment would have 6 participants and 3 participants for the control.

2.5. Eligibility Criteria: Inclusion, exclusion and withdrawal from the study

Participants who were considered qualified to join in this study included males and females between the ages 45–70 years diagnosed with a secondary dyslipidaemia. For the purposes of this study, these subjects were to have a raised total cholesterol (T−CHOL) level of >149 mg/dl together with an increased Very-Low-Density lipoprotein (VLDL-c) of >100 mg/dl and a Low-Density lipoprotein (LDL-c) of > 100 mg/dl. Participants were also to be free of any clinically significant diseases such as an endocrine disease and a pre-existing cardiovascular risk. Subjects were required to adhere to the protocol and provide an informed consent. Exclusions were based on the use of antilipemic and hypoglycaemic agents, such as HMG-CoA reductase inhibitor, bile acid binding resins, nicotinic acid or niacin, fibrate derivatives, cholesterol absorption inhibitors, α-glucosidase inhibitors, first and second-generation sulfonylureas, biguanides and meglitinides within 30 days before the screening period. Individuals with hepatic and renal impairment as well as the acutely ill were all excluded.

2.6. Treatment outcomes

2.6.1. Effectiveness of the product

The primary outcome of interest in this study was an improvement in non-HDL and HDL indices of participants receiving the herbal remedy *MCP-1*. After the 8 weeks study period, every participant should have experienced a reduction in at least one non-HDL parameter as well as an increase in HDL. Changes or otherwise were then compared to that of the control group for clinical benefits and statistical inferences on these outcomes. Secondary outcomes of interest were the effect of the product on fasting blood sugar (FBS), Body Mass Index (BMI), blood pressure (BP) and the atherogenic index of plasma (AIP) of participants.

2.6.2. Safety of the product

Safety evaluation was performed using the test values of creatinine, urea, sodium (Na^+), potassium (K^+) and chloride (Cl^-) for kidney function; alanine aminotransferase (ALT), aspartate transaminase (AST), alkaline phosphatase (ALP), γ-glutamyl transaminase (GGT), lactate dehydrogenase (LDH), total bilirubin (TBIL), total protein (TPROT) and albumin (ALB) for liver function. Haematological assessment was also determined using white blood cell count (WBC), red blood cell (RBC), haematocrit (HCT), haemoglobin (HGB) and platelet counts (PLT). Additionally, an active surveillance of harms was undertaken to identify any related adverse effects using a standardised World Health Organisation questionnaire.

2.7. Interventions

The herbal product, *MCP-1* is prepared from the leaves and twines of the plant *Momordica charantia.* The product in its traditional formula is charred and then packed as 50 g sachets with preparation instructions. Patients are advised to mix an equivalent of two teaspoonfuls of the product (about 4 g) with 150 mls of water and administer 3x daily either before or after meals. *MCP-1* used in this study was obtained directly from the manufacturer and had a batch identification number CH19002.

Dietary plans and recommendations used for the study were developed according to the guidelines issued by the Ottawa Cardiovascular Centre with modifications to the meals based on the cost and availability for participants (Ottawa Cardiovascular Centre, 2010). Briefly, the emphasis was on the consumption of locally available whole grain cereals, nuts, root tubers due to their complex carbohydrates and fibres. It was also recommended that participants consume vegetables, lean meat, plant-based oils and where practical, oily fish according to the servings indicated in the guidelines. Regular exercising and increased physical activity were also advised. This dietary plan was provided for all participants in both parts of the study.

2.8. Standardisation of MCP-1

MCP-1 comprising the dried leaves and twines of *Momordica charantia* was standardised using the flavonoid quercetin. The quercetin content in the product was assayed due to its antioxidant activity and the relevance of antioxidants in the prevention and management of CVD. The chromatographic system used comprised a Dionex Ultimate 3000 RS Pump HPLC, degasser, autosampler Dionex Ultimate XRS and a Dionex Ultimate RS diode array multiple wavelength detector. The column used was a BDS Hypersil C_{18} reverse phase column (120A pore size, Ø 4.6 mm x 150 mm). The mobile phase employed was Acetonitrile (ACN), methanol (MeOH) and 1% acetic acid (CH3COOH) (15: 40: 45) with a flow rate of 1.0 mL/min and injection volume of 20 µL. Column temperature was also kept at an ambient temperature of 26 °C and detection done at 365 nm. The product *MCP-1* is after assay was defined as having a quercetin content of 0.63 (± 0.004) mg/mL. Chromatographic fingerprint is attached as Fig. 2.

2.9. Sample size calculation and statistical analysis

The primary outcome hypothesized that participants receiving the herbal treatment *MCP-1* would have a bigger decline in triglycerides, TCHOL, VLDL-c, LDL-c and an increased HDL-c compared to subjects in the dietary control group.

Sample size calculation required a minimum of 10 participants in the treatment group based on the risk of a type II error of 0.20 and a change of 10.0 % in all lipid values at the end of the treatment. Type I error was set at 0.01 and the population SD assumed to be 2.00.

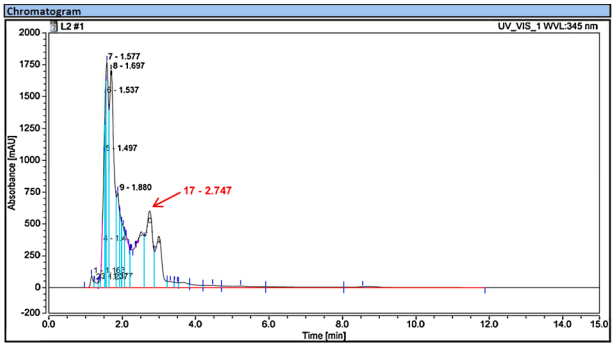

Fig. 2. Qualitative HPLC fingerprint for *MCP-1*. Quercetin appears as peak No 17 with a time of 2.747 min. Solvent system: Acetonitrile (ACN), methanol (MeOH) and 1% acetic acid (CH_3COOH) (15: 40: 45).

Column statistics followed by a one-way analysis of variance (ANOVA) with a Bonferroni *posthoc*-test was used to represent and compare the differences between the herbal treatment and the control groups. All data was analysed using the GraphPad Prism version 5.0 software and represented as the mean (SD). A p-value of <0.01 was considered as statistically significant.

3. Results

3.1. Study subjects

A total of 43 participants visiting the outpatient unit of the CPMR clinic were approached, recruited and screened for their eligibility to partake in the study. Based on the criteria, 21 participants qualified to be enrolled in the study. One eligible participant however decided to voluntarily opt out citing an aversion to needles after baseline data was acquired. A total of 20 participants were thus randomised as illustrated in Fig. 1.

The mean age of participants was 58.2 (± 8.36) years and 58.8 (± 7.86) years for *MCP-1* and the control groups respectively. The population demographics for subjects who completed the study is reported as Table 1. Baseline data obtained for the safety and efficacy assessment for the 2 populations were also comparable. A total of 5 subjects were lost at the first follow-up date. They comprised 3 (23.07 %) from the *MCP-1* group and 2 (28.57 %) from the control group. No reasons were assigned by these subjects for dropping out.

3.2. Safety evaluation of MCP-1

Investigators did not identify any untoward effects associated with the use of any of the interventions. An active surveillance method was used in this process of identifying potential side effects. Blood indices that could indicate potential organ damage from the use of the product were also absent. The renal function for the *MCP-1* group was not clinically different from participants assigned to the dietary intervention alone. Electrolytes, urea and creatinine for subjects remained unaffected by the treatment (Table 2). Similarly, hepatic function was also preserved over the 8 weeks of the study. Indices tested such as AST, ALP, ALB and GGT were also normal when compared to the control. Haematological assessment conducted as part of the safety evaluation did not indicate any untoward drug effects (Table 3).

3.3. Treatment efficacy

The primary outcome (defined as a decrease in at least one non-HDL parameter and an increase in HDL) was achieved for all participants in the treatment and control groups at the end of the study. There was a significant reduction in the mean LDL-c and VLDL-c of the treatment group compared to the control group (Table 5). LDL-c for subjects receiving *MCP-1* declined by 25.44 % compared to their baseline. VLDL-c also declined by 23.43 % for the same group. Changes to other lipid indices such as triglycerides, TCHOL and HDL were not statistically different from the control treatment ($p > 0.01$). A reduction of 3.35 % in triglyceride level was seen in the *MCP-1* group, TCHOL reduced by 9.78 % and HDL-c increased by 6.92 %. In the control group, HDL-c increased by 3.92 % while TCHOL reduced by 9.43 %.

Secondary outcomes, defined by improvements to disease-related indicators such as FBS, Systolic and Diastolic BP and BMI were not significantly different between the treatment and the control groups (Table 4). Similarly, AIP decline was also not statistically significant ($p >$ 0.01; CI: -0.0044 to 0.0027).

Table 1
Demographical data of participants who completed the 8-week study.

	MCP-1	Dietary Control
Age	58.2 (8.36)	58.8 (7.86)
Sex:		
Males n (%)	4 (40 %)	1 (20 %)
Females n (%)	6 (60 %)	4 (80 %)

Table 2
Results of the Liver and Renal Assessment for participants treated with *Momordica charantia* Powder compared to the Dietary control.

Parameter	*MCP-1*		Dietary Control		CI
	Baseline	End of Study	Baseline	End of Study	
AST	25.54 (6.17)	24.59 (4.38)	27.88 (6.39)	26.18 (3.63)	−6.51 to 3.33
ALT	25.90 (4.27)	25.64 (3.99)	25.80 (3.58)	24.96 (3.59)	−3.90 to 5.26
ALP	131.3 (22.22)	124.8 (11.55)	125.5 (16.75)	123.8 (11.40)	−12.59 to 14.63
GGT	18.52 (3.87)	18.06 (3.41)	19.88 (3.17)	18.56 (4.13)	−4.81 to 3.81
LDH	56.27 (7.05)	53.84 (5.67)	56.04 (3.51)	53.68 (3.10)	−5.78 to 6.10
TPROT	6.88 (0.47)	6.97 (0.42)	7.06 (0.27)	7.10 (0.38)	−0.61 to 0.35
ALB	3.82 (0.43)	3.95 (0.39)	3.90 (0.52)	3.82 (0.41)	−0.34 to 0.60
TBIL	10.76 (2.99)	10.11 (2.47)	11.20 (2.02)	10.58 (1.81)	−3.17 to 2.23
Na^+	138.8 (2.85)	138.2 (2.17)	137.8 (2.47)	137.9 (2.39)	−2.33 to 2.97
K^+	4.17 (0.50)	4.13 (0.47)	4.12 (0.37)	4.22 (0.38)	−0.62 to 0.44
Cl^-	99.23 (1.15)	98.90 (0.81)	98.66 (0.75)	98.74 (0.88)	−0.83 to 1.15
Urea	3.57 (0.67)	3.32 (0.62)	3.89 (0.23)	3.86 (0.34)	−1.18 to .116
Creatinine	80.26 (8.08)	79.28 (7.65)	78.57 (6.16)	77.72 (6.52)	−7.11 to 10.22

Data presented as Mean ±SD. (AST− aspartate transaminase, ALT− alanine aminotransferase, ALP− alkaline phosphatase, GGT− γ−glutamyl transaminase, Na+− sodium, K+−potassium, Cl−Chloride, LDH−lactate dehydrogenase, TBIL−total bilirubin, TPROT−total protein and ALB−albumin.

Table 3
Results from the Haematological Assessment conducted for the *Momordica charantia* Powder and Dietary Control groups.

Parameter	*MCP-16*		Dietary Control		CI
	Baseline	End of Study	Baseline	End of Study	
WBC	3.82 (0.85)	4.50 (0.42)	4.56 (0.93)	4.72 (0.67)	−0.82 to 0.380
RBC	5.06 (0.45)	4.93 (0.52)	5.17 (0.53)	5.15 (0.61)	−0.87 to 0.43
HCT	49.68 (1.78)	49.48 (1.99)	50.21 (1.89)	50.39 (2.55)	−3.49 to 1.67
HGB	12.96 (0.73)	13.21 (0.48)	12.73 (0.74)	12.80 (0.46)	−0.16 to 0.96
PLT	356.8 (63.49)	355.4 (65.75)	400.8 (23.58)	402.2 (25.27)	−113.6 to 19.97

Data presented as Mean ±SD. (WBC-White Blood Cells, RBC-Red Blood Cells, HCT-Haematocrit, HGB-Haemoglobin, PLT-Platelet).

4. Discussion

The safety and efficacy of *MCP-1* formulated as a charred material from the leaves and vines of *Momordica charantia* was assessed in this non-blinded comparative study. The study compared the interventional drug to a standard dietary regimen. Dietary recommendations for the control group were modified in line with the most available and cost-effective foods accessible for the participants. A pilot-scale trial was undertaken because it was a first attempt at clinically evaluating the

Table 4
Comparison of Disease Related Indicators for the Treatment and Control Group.

Parameter	*MCP-16*		Dietary Control		
	Baseline	End of Study	Baseline	End of Study	CI
FBS	6.58 (1.41)	6.24 (1.20)	6.48 (1.03)	6.60 (1.31)	−1.82 to 1.10
BP Systolic	144.2 (19.99)	136.5 (18.43)	128.8 (19.25)	126.0 (18.88)	−11.47 to 32.47
BP Diastolic	80.70 (8.51)	79.50 (6.67)	82.0 (8.22)	82.0 (9.06)	−11.36 to 6.36
BMI	27.54 (2.34)	27.15 (2.33)	26.12 (1.92)	25.42 (1.77)	−0.84 to 4.30

Data presented as Mean ±SD. (FBS-Fasting Blood Sugar, BP-Blood Pressure, BMI-Body Mass Index).

Table 5
Effect of *Momordica charantia* on the Blood Lipids after Treatment compared to the Control.

Parameter	*MCP-16*		Dietary Control		
	Baseline	End of Study	Baseline	End of Study	CI
TG	155.1 (33.97)	149.9 (29.29)	145.1 (8.21)	140.2 (7.55)	−19.48 to 39.02
TCHOL	160.6 (8.63)	144.9 (6.37) [a,b]	152.6 (2.81)	138.2 (16.64)	−5.825 to 19.37
LDL-c	123.1 (10.54)	91.78 (9.25) [a,c]	124.6 (11.95)	122.3 (8.68)	−41.24 to -19.76
VLDL-c	120.4 (10.56)	92.19 (6.47) [a,d]	122.1 (6.20)	109.7 (10.41)	−26.87 to -8.192
HDL-c	38.74 (2.77)	41.42 (1.64) [b]	39.03 (1.97)	40.56 (1.13)	−0.9122 to 2.632
AIP	0.057 (0.0057)	0.052 (0.0034)	0.055 (0.0031)	0.053 (0.0016)	−0.0044 to 0.0027

Data is expressed as Mean ± SD.
[a] $p < 0.001$.
[b] $p < 0.01$ compared to baseline after ANOVA and Bonferroni post−test.
[c] $p < 0.001$.
[d] $p < 0.01$ compared to the dietary control. (TG−Triglycerides, TCHOL−Total Cholesterol, LDL−Low Density Lipoprotein, VLDL−Very Low−Density Lipoproteins, HDL−High Density Lipoprotein, AIP− atherogenic index of plasma).

lipid lowering effect of this herbal product.

A total of 15 participants were able to complete the study from an initial population of 21. All attrition occurred before the first follow up hence was not included in the analysis. Fig. 1 summarises the trial procedure and results after termination of the study. Default rate for the study was 6 (28.57 %) participants. Significantly, this formulation of the plant was demonstrated to be safe from the results of the biochemical, haematological and monitoring of adverse/side effects of participants in the treatment group. Important biochemical indicators such as gamma glutamyl transferase (GGT), aspartate transaminase (AST), alanine transferase (ALT), Urea, Creatinine remained unchanged after treatment (Tables 2 & 3). Similarly, platelet function remained within the allowable limits as was the other haematological indicators (Table 4).

This profile of the product was essential as some groups have previously raised flags about the safety of *M. charantia*. It has been reported that lectins isolated from the seeds of the plant inhibit the development of lymphocytes *in vitro* (Licastro et al., 1980). Khan and his colleagues also noted the potential teratogenicity of the fruit and seed extracts when they reported it affects the cardiac myoblast specification process in zebra fish (Khan et al., 2019). Other reports, the first comparing plants from different regions showed a reduction in hatching among zebra fish and an increase in the incidence of scoliosis when exposed to relatively high concentrations of the plant extracts (Thiagarajan et al., 2019). The second conducted in Sprague Dawley rats documented an increased foetal malformation after administration of *M. charantia* (Uche-Nwachi and McEwen, 2010). Although majority of the adverse indications reported have been on the fruits and seeds, it is relevant to note that we may still need a more extensive assessment to make finite conclusions on the safety of *MCP-1*.

Efficacy assessment of *MCP-1* indicated lipid lowering action. Non-HDL levels saw a decline compared to the baseline (Table 5). Among the *MCP-1* group, triglycerides reduced by 3.46 % compared to 3.37 % for the control, while total cholesterol also reduced by 9.78 % and 9.43 % in the *MCP-1* and control respectively. HDL saw an increase (*MCP-1*: 6.92 % and Control: 3.92 %) after the 8 weeks of treatment. Compared to the control group who relied on a dietary recommendation, the treated group saw a greater decline in their lipidemic indices although differences were not statistically significant but for LDL (CI: -41.24 to -19.76) and VLDL (CI: -26.87 to -8.192).

The lipid lowering effect demonstrated by the plant has been investigated by numerous authors with a view to providing alternative remedies for patients with metabolic syndrome (Ahmed et al., 2001; Jayasooriya et al., 2000; Chen et al., 2003). Mechanistic explanation for this activity is multiple and chemically attributable to the presence of the mixture of steroidal saponins known as charantins, insulin-like peptides and alkaloids (Raman and Lau, 2011). The steroidal glycosides are hypocholesterolaemic and exert minor triglyceride lowering effects (Ling and Jones, 1995; Senanayake et al., 2004). A similar effect on triglycerides was observed in this study.

The essence of other chemical agents such as momorcharins, momordenol, momordicilin, cucurbitins, cucurbitanes and erythrodiol cannot be ignored given the multiple mechanism of action. Nerurkar and his coworkers indicated that HepG2 cells treated with bitter melon juice exhibited reduced cellular TAG synthesis and secretion of TAG (Nerurkar et al., 2008, 2005). The authors also reported that in HepG2 cells treated with bitter melon juice, mRNA expression of Microsomal Triglyceride Transfer Protein (MTP) was inhibited. MTP plays a pivotal role in the assembly and secretion of apoB-containing lipoproteins, and induces sterol regulatory element binding protein-Ic, which is one of the nuclear transcription factors responsible for modulating lipid and lipoprotein metabolism (Nerurkar et al., 2008).

The other disease related indices such as glycaemic control, blood pressure and BMI recorded a decline after treatment but again the difference compared to the control group were not significant. *M. charantia* has been reported as having vasculoprotective properties by Abas et al., who identified that rats treated with the plant had an increased nitric oxide level with malondialdehyde levels decreasing. Immunohistochemical staining of same also showed an increase in eNOS expression in the endothelial lining as well as a reversal of the morphological deterioration observed in the aortic tissues of the animals treated (Abas et al., 2015). Similarly, the weight reducing and glycaemic control of the plant has also been well discussed (Hossain et al., 2012; Miura et al., 2001; Shetty et al., 2005; Tahira and Hussain, 2014; Tan et al., 2008).

This study is a step that provides the authors a basis for an extensive trial of the Ghanaian herbal medicinal product *MCP-1*. When successful this product can be an alternative or to complement the standard lipid lowering agents. The absence of any adverse effects among the test population is an added advantage due to how poorly patients tolerate most conventional antilipidemics (Taylor et al., 2013). The cost of treatment can be significantly reduced because the product is relatively cheaper, $ 3.69 USD for a 2-week treatment. The raw materials are easily sourced in the country and widely used by most traditional medicine practitioners.

4.1. Limitations of the study

Although blinding was impossible to attain for this trial due to the interventions, its absence could have affected outcomes observed. The sample size used was also limiting, a larger sample size would have been more representative of the population and enhanced the translation of results.

4.2. Conclusion

Evidence obtained from this study shows the herbal medicine product, *MCP-1* as having lipid lowering effects. Although the size of the trial is a limitation, it may be concluded that the product can be effective in reducing LDL-c and VLDL-c. There is also the prospect of *MCP-1* improving the control of TCHOL, TRIG and HDL-c although the outcomes for these indicators were statistically non-significant. However, an expanded trial will be essential to confirm the safety and effectiveness of the product.

CRediT authorship contribution statement

Kwesi Prah Thomford, **Ama Kyeraa Thomford** and **Joseph Yorke:** were responsible for the design of the trial and all the processes prior to ethical clearance.

Kwesi Prah Thomford and **Ronald Yeboah:** were involved in the data collection and the roll out of the trial.

Kwesi Prah Thomford, **Ronald Yeboah** and **Alfred Ampomah Appiah:** undertook the analysis of the data obtained.

Kwesi Prah Thomford and **Alfred Ampomah Appiah:** drafted the manuscript.

Joseph Yorke, **Ronald Yeboah** and **Alfred Ampomah Appiah:** reviewed the draft.

Declaration of Competing Interest

None declared.

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