

MINIMUM STANDARDS FOR HIJAMA THERAPY IN THE MALDIVES



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1. INTRODUCTION

In traditional Arabian medicine, Hijama means sucking (cupping), and it includes wet and dry cupping, but in Arabian culture, Hijama usually refers to wet cupping. Hijama is performed by Muslims as it is a form of medicine specifically mentioned and encouraged by the Prophet Muhammad (SAW) (Khalil et al., 2018). Hijama therapy has historical, traditional and religious value. It is increasingly popular in the field of complementary, alternative and integrative medicine. Although it is generally considered safe, Hijama therapy can cause adverse events, which are predictable and preventable (Siregar, Setyawan & Syahruramadhani, 2021).

There are many risks which can arise from unregulated services. The main risks arising from the practice of unregulated complementary and traditional therapies including Hijama therapy are not those directly related to the therapies themselves, but the indirect risks due to limitations in the therapists' diagnostic and clinical knowledge, skills and the lack of infection control measures. It is evident that such therapies need to be regulated and monitored to ensure safety of its users.

The purpose of this standard is to establish regulations for Hijama Therapy centers, encompassing the services provided, the practitioners involved, and the equipment used. The Maldives Allied Health Council oversees registration, and development of the scope of practice for Hijama Therapists, in accordance with Section 41 of Act No. 13/2015 (Health Professionals Act).

2. DEFINITIONS

Hijama therapy	“Wet cupping or Hijama means expansion, sucking, and bloodletting which is a procedure for bloodletting from the capillary networks after sucking and scarification steps. In this procedure, a cup is mostly attached to the surface of the skin by using a negative pressure or suction-like force. A few minutes later, the uplifted cup is removed, and superficial incisions are made using a scalpel. The cup is then replaced, and the procedure is repeated three to five times until some blood and interstitial fluid are drained” (Ghods, Sayfour & Ayati, 2016).
Hijama centre	Centre registered for providing Hijama therapy
Hijama therapist	Person who fulfils requirements of Maldives Allied Health Council and registered and licensed.
Maldives Allied Health Council	The council formed under S.41 of the Act No. 13/2015 (Health Professionals Act) to regulate the practice, registration and licensure of allied health professionals of the Maldives.

3. INFRASTRUCTURE REQUIREMENTS

Any person providing Hijama therapy shall have a dedicated space allocated to provide services. The place shall observe all mandatory requirements in chapter 3 of the regulation No. 2021/R-28 (Regulation on Operating Healthcare Centres). The floor plan of the Hijama centre shall be submitted along with registration form when applying for registration. All Hijama Centres operating in the Maldives shall fulfill structural requirements stipulated in criteria for grading of private health facilities.

4. MEDICAL DEVICES/CONSUMABLES

All medical devices/consumables used for Hijama therapy shall fulfil requirements stipulated in 24 of chapter 3 of Regulation no. 2021/R-28 (Regulation on Operating Healthcare Centres). The following are medical devices that shall be available (not limited to Individualized Hijama centre).

1. Autoclave
2. Disposable lancets/blades/ auto lancets
3. Cups (disposable or reusable)
4. Cupping suction pumps
5. Gauze bandage
6. Cotton
7. Surgical gloves
8. Hand sanitizers
9. Skin disinfectants
10. Surface disinfectants
11. Foot operated waste bins (different bins for different purposes)
12. Surgical mask
13. Sharp bins
14. Aprons/gown for staff
15. Apron gown for patient

5. REGISTRATION AND OPERATING LICENSE REQUIREMENTS

All Hijama centres shall obtain registration from Ministry of Health in accordance with provisions in chapter 4 of the regulation No. 2021/R-28 (Regulation on Operating Healthcare Centres). Additionally, operating license is required as stipulated in section 39 of the same regulation. The following are requirements for The Hijama centre and the therapist.

5.1 *For Hijama Centre*

- a) All Hijama Centres shall meet the below mentioned standards to be registered as a health facility providing Hijama therapy.
 - i. Shall meet infrastructure requirements outlined in chapter 3 of the regulation No. 2021/R-28 (Regulation on Operating Healthcare Centres).
 - ii. All documents required for registration are submitted along with completed health facility registration form.
 - iii. Letter of endorsement from Maldives Allied Health Council stating required document set is submitted to the council for professional registration and license.
 - iv. Fully paid amount required for the registration.
- b) Operating license shall be granted upon fulfilling the following requirements:
 - i. Valid registration certificate of the Hijama centre from QARD.
 - ii. Hijama therapist having a valid registration and license from Maldives Allied Health Council.
 - iii. All medical devices and consumables specified in section 4 of this standard are available at the Hijama centre.
 - iv. Standard operating procedures for infection prevention and control, process flow, referral mechanisms and other relevant SOPs for the functionality of the facility shall be developed.
 - v. The term of Hijama Centre's operating license shall be five years and the Centre shall renew it one month before its expiry.

5.2 For Hijama Therapist registration

QARD shall include Hijama therapist's name on the health professionals register who is permitted to practice at the centre. The therapist's name may be added to the list upon meeting the following criteria:

- 5.2.1 Having a valid registration certificate/practicing license from Maldives Allied Health Council.
- 5.2.2 Completed hours of training requirements set out by Maldives Allied Health Council.
- 5.2.3 The applicant should be free of infectious diseases, including the Acquired Immune Deficiency Syndrome (AIDS), viral hepatitis (B and C) and Tuberculosis.

6. RESPONSIBILITIES

All Hijama Centres shall ensure below underlined points.

- 6.1 Have registration and operating license in a safe place so that it could be seen by the clients and regulatory authorities.
- 6.2 Shall have Hijama therapist(s) registered to practice at the centre.
- 6.3 Hijama therapists and the centre shall abide by the code of conduct for health professionals and other relevant laws and regulations.
- 6.4 The Hijama Centre and the therapist shall be subject to provisions in Act No. 15/2015 (Health Professionals Act) in the event of negligence and breach of duty of care.
- 6.5 The Hijama centre and the Hijama therapist shall abide by the standards and controls in this standard including updates to the standards by Ministry of Health in the future.
- 6.6 The suitability of Hijama for a patient should be evaluated carefully in terms of their general health and the specific risks associated with Hijama. An individual's risk for various adverse events should be determined during the initial assessment. Transfer to a health facility if their health condition so requires during the assessment.
- 6.7 All client records shall be maintained in accordance with Regulation No. 2019/R-1070 (Regulation on Medical Records). This includes minimum information that shall be

reflected on client progress files and duration shall be maintained and hard and soft copies conserved.

- 6.8 Where required medical devices and consumables shall be registered at Maldives Food and Drug Authority.
- 6.9 Re-usable cups **SHOULD ONLY** be used for single person and the cups **MUST** be cleaned thoroughly and autoclaved. If the autoclave date pass 14 days it **MUST** be re-autoclaved.
- 6.10 The therapist shall complete number of continuous professional development hours as required by Maldives Allied Health council.
- 6.11 Hijama centres shall refrain from advertising services except after obtaining prior approval from QARD. All Hijama centres are subject to provisions in section 7 of Regulation No. R-21/2021 (Regulation on Operating Health Facilities).
- 6.12 Hijama centres shall only advertise claims that is evidence based, and prior approval shall be obtained from QARD before publicly announcing.
- 6.13 All Hijama Centres shall abide by the provisions in chapter 6 of regulation No. 2021/R-28 (Regulation on Operating Health facilities), which indicates all services and their prices shall be visible for the people seeking its services.
- 6.14 All Hijama therapists shall have completed their vaccinations
- 6.15 Hijama Centre shall not:
 - a) Employ unlicensed therapists to provide assistance to any person illegally practicing any type of Hijama Therapy
 - b) Practice therapies that exceed the competence, scope of practice or capabilities thereof.

7. CRITERIA FOR HIJAMA THERAPY

- 7.1 All Hijama centres shall conduct a health assessment on all clients seeking Hijama Therapy. Client assessment form in figure 1. Client assessment form shall have header and footer of the Hijama Centre.
- 7.2 Client eligibility to Hijama Therapy shall be decided based on the assessment.
- 7.3 Client seeking Hijama Therapy shall be well informed about the sessions, type of Hijama and steps of the Hijama sessions.
- 7.4 Clients with phobia to sharp objects or blood should be discussed how to manage or terminate sessions.

Figure 1: Client assessment form

CLIENT ASSESSMENT FORM		
Name of the client:		Date of birth:
NIC/PP number:		Age:
Address:		Gender:
Medical history <i>(indicate the diagnosis of patient if any)</i>		
Medical illness <i>(please tick in below boxes if diagnosed)</i>	Recent symptoms	Details of treatment
<input type="checkbox"/> Diabetes Mellitus <input type="checkbox"/> Cardiovascular disease & pacemakers <input type="checkbox"/> Cancer <input type="checkbox"/> Blood diseases <input type="checkbox"/> Organ failure <input type="checkbox"/> Hepatitis <input type="checkbox"/> HIV/AIDS <input type="checkbox"/> Fractures/surgery <input type="checkbox"/> Is the patient on anticoagulant therapy?		
Family history		
Medication history (including herbal remedies)		
6. Precaution for female clients: 7. Are you pregnant? <input type="checkbox"/> No: Date of last menstrual period:..... <input type="checkbox"/> Yes: Estimated gestational age:.....weeks		Do you have history of miscarriages? <input type="checkbox"/> None: <input type="checkbox"/> Yes:times Cause of miscarriages.
Physical examination		
Vital signs Temperature: Blood pressure: Pulse and Respiratory rate Weight & height		Other examinations
Diagnosis and eligibility		
Health diagnosis <input type="checkbox"/> Healthy client <input type="checkbox"/> Minor health issue <input type="checkbox"/> Major health issue		Is the client eligible for Hijama <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No for specific method
Name of person conducting assessment..... Designation..... Date.....Signature.....		
Official stamp of the Hijama Centre		

Adapted from Siregar et al. (2021). A model to standardize safety and quality of care for cupping therapy.

8. INFECTION PREVENTION AND CONTROL MEASURES

ALL Hijama centres shall ensure the following:

- 8.1 Have SOP for infection prevention and control, needle stick injuries and its post exposure prophylaxis, waste management at the centre in accordance with national guideline on infection prevention and control. Additional SOP is requiring extra precaution/ cleaning and disinfection of equipments used by positive clients.
- 8.2 Have all equipment/consumable necessary for autoclaving.
- 8.3 Use of skin disinfection before performing any procedure on the client.
- 8.4 Where necessary, use Personal Protective Equipment (PPE) when attending clients.
- 8.5 Segregation at the point of waste generation and onsite treatment before sending off for disposal. Shall also have a dedicated space for storage of waste before sending off.
- 8.6 All practices at the centre shall be in line with national guideline on infection prevention and control, which includes hand washing, use of personal protective equipment, instrument disinfection & sterilization, waste disposal, etc.
- 8.7 Investigations may be required prior to the session depending on the condition of the client.
- 8.8 Where needed the therapist and the client need to be vaccinated.

9. CONTRA INDICATIONS FOR HIJAMA THERAPY

Figure 2: Conditions where Hijama therapy is contraindicated

Targeted area of Hijama	Relative	Absolute
	<ul style="list-style-type: none"> - Skin grafts - Skin inflammations, infection, abscess and ulcers - Aging skin - Eczematous skin 	<ul style="list-style-type: none"> - Orifices (eye, ear, nose, mouth etc.) - Vein, artery, nerve, and lymph node area (including varicose veins and deep vein thrombosis) - Extremity joint, knee and elbow - Abdomen in pregnancy - Deranged skin, open wound and sunburns.
Condition of client	<ul style="list-style-type: none"> - Hb 9-12mg/dl - Diabetes mellitus - Cardiovascular disease and pacemaker users - Cancer - Blood disease - Organ failure - Blood borne infections (Hepatitis and HIV) - Recent fracture and surgery - Pregnancy, puerperium, and menstruation 	<ul style="list-style-type: none"> - Hb <9mg/dl - Extreme pain and tiredness - Extreme hunger or satiation - Non-cooperative patient (manic episode, and non-attentive children) - Hypotension (SBP <90mmHg or DBP <60mmHg in adults) - Medical emergencies (including hypertensive emergencies) - Acute vesico-bullous disease - Recent use of Anticoagulants (< 1 week) - Recent wet cupping sessions or blood donation (<1 week)

Adapted from Siregar et al. (2021). A model to standardize safety and quality of care for cupping therapy.

Hijama should not be conducted on children under 12 years of age (according to ministry's National Center for Complementary and Alternative Medicine (NCCAM) - Saudi Arabia), cancer patients (active and undergoing chemotherapy or related therapies), kidney patients undergoing dialysis (relative contraindication), liver failure and blood diseases like Hemophilia.

10. INFORMED CONSENT

All Hijama centres shall have obtained consent from the clients after through explanation of the procedure. The Hijama centre shall have their own consent forms and shall include minimum information as in Figure 3. It shall be written in clear Dhivehi language to ensure all seeking Hijama services clearly understand its content.

Figure 3: Informed consent

Informed consent	
<p>Hijama is generally considered safe. Some Hijama related events are mild expected to disappear within a few minutes to several days without special treatment. some of the discomforts you may feel are:</p> <ul style="list-style-type: none"> - Discomfort or local pain - Feeling cold or hot - Nausea and vomiting - Tiredness, sleepiness or insomnia - Headache - Erythema 	
<p>I/under my guardianship <u>(Name of the client)</u> hereby agree to get Hijama therapy for <u>(reason for Hijama therapy)</u> form <u>(name of the Hijama Therapist)</u>. The procedure and the risks have been explained to me by (name of the person explained). And I understand overall procedure and its possible adverse events. Also I was given the correct information regarding my health condition. Therefore, I consent to get Hijama Therapy.</p>	
Name of the client:	Name of the Hijama Therapist:
Date:	Date:
Signature	Signature and official stamp

11. DOCUMENTATION REPORTING

All documents regarding patient shall be maintained safely and stored in accordance with Regulation No. 2019/R-1070 (Regulation on Medical Records). All Hijama centres operating in the Maldives shall report the information in annex 1 of this standard.

12. AUDITING AND SANCTIONS

- 12.1 QARD shall monitor and valuate all activities of the licensees to practice Hijama on clients
- 12.2 Officials assigned by QARD shall undertake inspections and detect violations of Hijama Centre and Therapists
- 12.3 QARD shall have the right to penalties on negligence and breach of duty of care.
- 12.4 Hijama therapist shall be subject to professional and disciplinary liabilities under the Law No. 13/2015 (Health professionals Act).
- 12.5 The Hijama Centre shall be subject to penalties stipulated in Act No. 29/2015 (Health Service Act).

13. REFERENCES

- Ghods, R. Sayfour, N & Ayati, M. S. (2016). Anatomical Features of the Interscapular Area Where Wet Cupping Therapy Is Done and Its Possible Relation to Acupuncture Meridians. *Journal of Acupuncture and Meridian Studies*, 9(6), 290-296.
- Khalil., Et al. (2018). Cupping therapy in Saudi Arabia: From control to integration. *Integrative Medicine Research*, 7 (3),214-218.
- Siregar, R., Setyawan, A., & Syahruramadhani, S. (2021). A model to standardize safety and quality of care for cupping therapy. *Journal of Integrative Medicine*, 19 (4), 327-332.

Annex 1: Data template for Hijama therapy centres

Data Template of Hijama Procedure

Name of the health facility.....

Registered Address:

S.No	Age	Sex	Pre investigation done (Yes or No)	Type of cupping	Reason for Hijama therapy	Advised by	Name of Hijama therapist	Any adverse reaction after therapy	Regular medication	Any comorbidities	Number of Sessions

Total number of patients for the month of (month):

Note: Please fill this sheet and forward it to the Quality Assurance Division through email (qa@health.gov.mv) before the 5th of each month for the previous month