今天是：2024-01-16 星期二

非酒精性脂肪肝行为疗法

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注册号: Registration number:	ChiCTR-ONRC-13003751
最近更新日期: Date of Last Refreshed on:	2016-05-15
注册时间: Date of Registration:	2013-10-30
注册号状态:	预注册
Registration Status:	Prospective registration
注册题目:	非酒精性脂肪肝行为疗法
Public title:	Behavioral therapy of nonalcoholic fatty liver disease (NAFLD)
注册题目简写:	
English Acronym:	
研究课题的正式科学名称:	非酒精性脂肪肝生活质量评价系统及行为干预治疗新策略
Scientific title:	Evaluation system of quality of life and new strategy on behavioral therapy of nonalcoholic fatty liver disease (NAFLD)
研究课题代号(代码): Study subject ID:	
在二级注册机构或其它机构的注册号: The registration number of the Partner Registry or other register:	

申请注册联系人:	史琦玉	研究负责人:	宓余强
Applicant:	Qiyu Shi	Study leader:	Yuqiang Mi
申请注册联系人电话: Applicant telephone:	+86 [redacted]	研究负责人电话: Study leader's telephone:	+86 022-27468003
申请注册联系人传真 : Applicant Fax:		研究负责人传真: Study leader's fax:	
申请注册联系人电子邮件: Applicant E-mail:	shiqiyu2012@126.com	研究负责人电子邮件: Study leader's E-mail:	yuqiangmi68@163.com
申请单位网址(自愿提供): Applicant website(voluntary supply):		研究负责人网址(自愿提供): Study leader's website(voluntary supply):	
申请注册联系人通讯地址:	天津市南开区苏堤路75号天津市第二人民医院	研究负责人通讯地址:	中国天津市南开区苏堤路75号天津市第二人民医院
Applicant address:	75 Suti Road, Nankai District, Tianjin, China	Study leader's address:	75 Suti Road, Nankai District, Tianjin, China
申请注册联系人邮政编码: Applicant postcode:	300000	研究负责人邮政编码: Study leader's postcode:	300000
申请人所在单位:	天津市第二人民医院		
Applicant's institution:	Tianjin Second People's Hospital		
研究负责人所在单位:	天津市第二人民医院		
Affiliation of the Leader:	Tianjin Second People's Hospital		

是否获伦理委员会批准:	是		
Approved by ethic committee:	Yes		
伦理委员会批件文号:	津传伦审字[2012]06号	伦理委员会批件附件:	

Approved No. of ethic committee:	Approved file of Ethical Committee:
批准本研究的伦理委员会名称:	天津市传染病医院伦理委员会
Name of the ethic committee:	Ethics Committee of Tianjin Infectious Disease Hospital
伦理委员会批准日期: Date of approved by ethic committee:	2012-02-22
伦理委员会联系人:	
Contact Name of the ethic committee:	
伦理委员会联系地址:	
Contact Address of the ethic committee:	
伦理委员会联系人电话: Contact phone of the ethic committee:	伦理委员会联系人邮箱: Contact email of the ethic committee:

研究实施负责（组长）单位:	天津市第二人民医院
Primary sponsor:	Tianjin Second People's Hospital
研究实施负责（组长）单位地址:	天津市南开区苏堤路75号天津市第二人民医院
Primary sponsor's address:	75 Suti Road, Nankai District, Tianjin, China

试验主办单位(项目批准或申办者): Secondary sponsor:

国家:	中国	省(直辖市):	天津	市(区县):
Country:	China	Province:	Tianjin	City:
单位(医院):	天津医科大学第二医院	具体地址:		
Institution hospital:	The Second Hospital of Tianjin Medical University	Address:		
国家:	中国	省(直辖市):	天津	市(区县):
Country:	China	Province:	Tianjin	City:
单位(医院):	天津医科大学总医院	具体地址:		
Institution hospital:	General Hospital of Tianjin Medical University	Address:		
国家:	中国	省(直辖市):	天津	市(区县):
Country:	China	Province:	Tianjin	City:
单位(医院):	天津市第一中心医院	具体地址:		
Institution hospital:	Tianjin First Central Hospital	Address:		

经费或物资来源:	天津市卫生局科技基金
Source(s) of funding:	Science and Technology Fundation of Tianjin Municipal Health Bureau
研究疾病:	非酒精性脂肪性肝病
Target disease:	nonalcoholic fatty liver disease
研究疾病代码:	
Target disease code:	
研究类型:	观察性研究
Study type:	Observational study
研究所处阶段:	探索性研究/预试验
Study phase:	0
研究设计:	非随机对照试验
Study design:	Non randomized control
研究目的:	1.明确非酒精性脂肪性肝病（nonalcoholic fatty liver disease,NAFLD）患者的生活质量情况，建立NAFLD患者的 生活质量评价系统； 2.优化NAFLD患者的行为治疗策略，建立NALFD临床路径；3.建立NAFLD患者行为干预治疗依从性预测模型。
Objectives of Study:	1. To investigate the quality of lives of nonalcoholic fatty liver disease (NAFLD) patients, and to establish evaluation system of the quality of lives of NAFLD patients; 2. To optimize the strategy of behavioral therapy of NAFLD patients, and to establish clinical pathway of NAFD; 3. To modelling prediction of adherence on behavioral therapy of NAFLD patients.
药物成份或治疗方案详述:	

Description for medicine or protocol of treatment in detail:	
纳入标准:	1.据中华医学会肝病学分会脂肪肝和酒精性肝病学组2010年修订的《非酒精性脂肪性肝病诊疗指南》明确诊断存在非酒精性脂肪性肝病（nonalcoholic fatty liver disease,NAFLD）的患者 2.年龄18-70岁，男女不限 3.ALT或AST<80 u/L 4.患者知情同意接受本试验
Inclusion criteria	1. Diagnosis of non-alcoholic fatty liver disease (NAFLD) according to Guidelines for diagnosis and treatment of nonalcoholic fatty liver disease revised by Fatty Liver and Alcoholic Liver Disease Study Group of the Chinese Liver Disease Association in 2010; 2. Males or females aged from 18-70 years old; 3. ALT or AST less than80 u/L; 4. Informed consent has been obtained before commencement of the study.
排除标准:	1.曾有酒精摄入>20g/天饮酒史患者 2.合并存在其他肝病患者（如病毒性、药物性、自身免疫性肝病等） 3.疑有肝硬化、肝细胞癌患者 4.伴有其他严重全身性疾病或感染性疾病，如：恶性肿瘤、严重心肺疾患、神经系统疾病、HIV感染等 5.因疾病或其他原因无法进行饮食控制及有氧运动 6.孕妇、哺乳期妇女、在试验中怀孕或准备受孕的育龄妇 7.合并精神疾病或严重神经官能症患者，或由于智力或语言障碍，不能表达主观不适症状，妨碍与研究者的交流与合作者
Exclusion criteria:	1. History of Alcohol intake>20g/d; 2. Co-existing of other liver diseases, such as viral, drug-induced, auto-immune hepatitis and so on; 3. Suspicion of liver cirrhosis or liver cancer; 4. Co-existing of other severe systematic disease or infectious disease, such as malignant neoplasm, severe cardiopulmonary disease, neurological disorders, HIV infection and so on; 5. Unable to control diet or to conduct aerobic exercise; 6. Currently pregnant, breastfeeding, pregnancy anticipated during study or planning to be conceive; 7. Co-existing of mental disorders or severe neurosis, or unable to express symptoms subjectively and hindering connection and cooperation with researchers because of dysgnosia or aphasis.
研究实施时间: Study execute time:	从 From 2013-11-01至 To 2015-10-05
征募观察对象时间: Recruiting time:	从 From 2013-12-01 至 To 2014-10-01

干预措施: Interventions:

组别:	观察组	样本量:	250
Group:	Obervation group	Sample size:	
干预措施:	运动及饮食	干预措施代码:	
Intervention:	Diet and exercise	Intervention code:	
组别:	验证	样本量:	125
Group:	control	Sample size:	
干预措施:	NA	干预措施代码:	
Intervention:	NA	Intervention code:	

研究实施地点: Countries of recruitment and research settings:

国家:	中国	省(直辖市):	天津	市(区县):
Country:	China	Province:	Tianjin	City:
单位(医院):	天津市第二人民医院	单位级别:	三级甲等医院	
Institution hospital:	Tianjin Second People's Hospital	Level of the institution:	Tertiary A hospital	
国家:	中国	省(直辖市):	天津	市(区县):
Country:	China	Province:	Tianjin	City:
单位(医院):	天津医科大学第二医院	单位级别:	三级甲等医院	
Institution hospital:	The Second Hospital of Tianjin Medical University	Level of the institution:	Tertiary A hospital	
国家:	中国	省(直辖市):	天津	市(区县):
Country:	China	Province:	Tianjin	City:
单位(医院):	天津医科大学总医院	单位级别:	三级甲等医院	
Institution hospital:	General Hospital of Tianjin Medical University	Level of the institution:	Tertiary A hospital	
国家:	中国	省(直辖市):	天津	市(区县):
Country:	China	Province:	Tianjin	City:

单位(医院):	天津市第一中心医院	单位级别:	三级甲等医院	
Institution hospital:	Tianjin First Central Hospital	Level of the institution:	Tertiary A hospital	

测量指标: Outcomes:

指标中文名:	体重	指标类型:	主要指标
Outcome:	Weight	Type:	Primary indicator
测量时间点:		测量方法:	
Measure time point of outcome:		Measure method:	
指标中文名:	腰围	指标类型:	主要指标
Outcome:	Waist	Type:	Primary indicator
测量时间点:		测量方法:	
Measure time point of outcome:		Measure method:	
指标中文名:	肝功能	指标类型:	主要指标
Outcome:	Liver function	Type:	Primary indicator
测量时间点:		测量方法:	
Measure time point of outcome:		Measure method:	
指标中文名:	血脂	指标类型:	主要指标
Outcome:	Blood lipid	Type:	Primary indicator
测量时间点:		测量方法:	
Measure time point of outcome:		Measure method:	
指标中文名:	血糖	指标类型:	主要指标
Outcome:	Blood glucos	Type:	Primary indicator
测量时间点:		测量方法:	
Measure time point of outcome:		Measure method:	

采集人体标本: Collecting sample(s) from participants:

标本中文名:	血液	组织:	
Sample Name:	Blood	Tissue:	
人体标本去向	使用后销毁	说明	
Fate of sample:	Destruction after use	Note:	

征募研究对象情况: Recruiting status:	结束 /Completed	年龄范围: Participant age:	最小 Min age 18 岁 years 最大 Max age 70 岁 years
性别:	男性	Gender:	Male
随机方法（请说明由何人用什么方法产生随机序列）:	非随机		
Randomization Procedure (please state who generates the random number sequence and by what method):	non radomized		
是否公开试验完成后的统计结果: Calculated Results after the Study Completed public access:	公开/Public		
盲法:			
Blinding:			
试验完成后的统计结果（上传文件）:	点击下载		
Calculated Results after the Study Completed(upload file):	download		
是否共享原始数据: IPD sharing			

共享原始数据的方式（说明：请填入公开原始数据日期和方式，如采用网络平台，需填该网络平台名称和网址）：	NA
The way of sharing IPD”(include metadata and protocol, If use web-based public database, please provide the url):	NA
数据采集和管理（说明：数据采集和管理由两部分组成，一为病例记录表（Case Record Form, CRF），二为电子采集和管理系统(Electronic Data Capture, EDC)，如ResMan即为一种基于互联网的EDC：	NA
Data collection and Management (A standard data collection and management system include a CRF and an electronic data capture:	NA
数据与安全监察委员会：Data and Safety Monitoring Committee：	

返回列表

中国临床试验注册中心 - 世界卫生组织国际临床试验注册平台一级注册机构
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提示：推荐使用IE8.0以上版本 宽屏显示分辨率下使用系统